

# STOCKHOLM INTELLECTUAL PROPERTY LAW REVIEW

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## Editorial

The Stockholm Intellectual Property Law Review was established within the auspices of the Master's Programme of European Intellectual Property Law at Stockholm University – a programme that was initiated by Professor Marianne Levin and welcomed its first students in early January 2000. The students came from different parts of the world, and the lectures would usually take place at the picturesque wooden house 'Juristernas Hus' ('The Law Student's House') on the Stockholm University campus. In particular for international students adjusting to the extremely cold winter of 2000, getting acquainted with the Swedish university system and its pedagogical approach was a challenge. However, what warmed up the environment was the feeling that you had actually been welcomed into a 'family' of IP enthusiasts, a 'family' led by the fashionable and renowned IP connoisseur Marianne Levin, with the assistance of her doctoral candidates. This feeling, which is really very difficult to describe on paper, followed you throughout the studies, and afterwards – even after graduation – you continued to be part of the alumni network of the programme. It is characteristic that among the group of Master's students of this first year, two eventually went on to write doctoral dissertations in IP at Stockholm University.

In 2000, European IP law was in a state of transformation. The advent of the internet in the 1990s profoundly changed the way in which we communicate, use and share information and intellectual resources. In 1994, the TRIPS agreement fuelled the globalisation of IP and recognised the need for global cooperation in the field of minimum standards for protection and sanctions. Sweden's accession to the European Union in 1995 marked the entrance of Swedish IP law into the European Union legal framework, including its IP regulations, and ended the national (and Nordic) exceptionalism in that sector. It was in this environment that the Master's programme was born.

The creation of the Master's programme seemed like a natural expansion of the vibrant research and teaching environment that Marianne Levin had created at the Department of Law at Stockholm University. In the early 2000s, her research group consisted of around ten doctoral candidates, but it would gradually expand even further. The group covered a broad spectrum of IP law and marketing law, e.g., likelihood of confusion and protection of reputation in trademark law, unconventional trademarks, copyright and databases, consumer protection and trading law, employees' IP rights, patents and biotechnology, damages in patent law and protection for traditional knowledge and natural resources. Marianne nurtured the research endeavours of her doctoral candidates and the hub that she created was unique in its diversity and scope. It was an unrivalled achievement. It was only natural that the Master's programme grew out of this unique environment, with plentiful resources for teaching and a strong connection between research and teaching.

Beyond resources from the internal research group at Stockholm University, the teachers, examiners and supervisors engaged in the Master's programme were part of Marianne's international research network. These were colleagues from Denmark, Finland, Norway, Germany, France, the US and other countries, who enhanced the teaching staff as guest lecturers. This amazing international network of prominent researchers would gather in Stockholm, even in the cold winter months, to deliver lectures, supervise students and discuss the prospect of

new research projects with Marianne and the doctoral candidates. The IP Nordic Network was actively involved in this initiative, and the programme included several teachers and students from other Nordic countries.

Marianne has always been able to identify future IP talents and either attract them to the university to pursue an academic career or encourage them to work at law firms or companies. She has in that way gradually built up a network of IP professionals who owe her their inspiration and interest in IP. Further, it has always been amazing to watch how she is able to enchant and engage students in her projects, activities and competitions, whether IP-related or not. The programme is a result of Marianne's devotion to developing the field of IP law by recognising and supporting young students with a passion for that field. Her network of former students and amanuenses comprises private practitioners, professors, company lawyers, CEOs, ministry officials and others – in Sweden and internationally. Such has been the impact of the programme that the alumni network now stretches to all parts of the world (perhaps excluding Antarctica?). Even while juggling the position of a professor and expert with many projects and responsibilities, including as Chair of the Swedish Association for Intellectual Property Law (SFIR), guiding junior researchers in the field of IP law has always been one of Marianne's passions and an influential part of her legacy. Marianne continues to work as a teacher within the Master's programme and the undergraduate law programme, and many young IP law students still benefit from her advice and support. She also actively supports the work of the Stockholm IP Law Review!

Our warmest congratulations to Marianne on her birthday – and we are looking forward to many more!

*Åsa Hellstadius & Frantzeska Papadopoulou*



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## Lettre à Marianne

Très chère Marianne, si je t'écris cette lettre en français, ce n'est pas seulement parce que nous conversons de temps à autre dans la langue de Molière, mais c'est aussi et surtout parce que le français est ma langue maternelle, donc la langue du cœur. Et c'est mon cœur autant que mon cerveau qui dicte mes mots aujourd'hui.

Cela fait une quarantaine d'années que nous nous connaissons. Si je me souviens bien, c'est dans le cadre d'un des premiers congrès de l'Association internationale pour la promotion de l'enseignement et de la recherche en propriété intellectuelle (ATRIP), tenus à Genève dans les années 1980, que je t'ai rencontrée pour la première fois. Ta personnalité chaleureuse et enthousiaste m'avait frappé et j'avais alors nourri l'espoir que nous pourrions nous revoir un jour ou l'autre, et ce vœu s'est plus que réalisé !

Sautons la fin du 20<sup>e</sup> siècle et venons-en au 21<sup>e</sup>. Pour moi, le début du nouveau siècle fut d'abord marqué par la fin de mon activité officielle à l'Organisation Mondiale de la Propriété Intellectuelle (OMPI) et ma reconversion vers l'enseignement, qui m'a toujours passionné, ce qui est un point commun avec toi. Nommé Professeur associé au Centre d'Etudes Internationales de la Propriété Intellectuelle (CEIPI) mais à temps partiel, j'étais disponible pour d'autres engagements. C'est alors que tu m'as proposé de te joindre à l'équipe travaillant sur le projet intitulé « Intellectual Property Rights in Transition (IPT) » que tu avais lancé et que tu dirigeais avec Annette Kur. Je te serai toujours reconnaissant de m'avoir impliqué dans ce fascinant projet, qui en plus de son grand intérêt intellectuel m'a permis de rencontrer et d'apprécier plusieurs spécialistes de la propriété intellectuelle des pays nordiques. J'ai ainsi participé à pas moins de 22 séances, dont 19 à Stockholm, entre 2002 et 2008. Rééquilibrer le système mondial de la propriété intellectuelle tel qu'il s'était matérialisé dans le fameux Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (Accord sur les ADPIC ou TRIPS Agreement) en mettant au point un texte alternatif a été l'ambition du projet IPT. Vu mon parcours professionnel, j'étais particulièrement intéressé par la volonté de prévoir en faveur des principales victimes de l'Accord sur les ADPIC, à savoir les pays en développement, des dispositions fixant des maxima de protection alors que l'Accord ne prévoit que des minima permettant aux pays dits développés et à leurs industries, notamment l'industrie pharmaceutique, d'imposer leur position de dominants sur le reste du monde. Bien sûr, je ne me faisais guère

d'illusions sur l'acceptabilité de nos propositions sur le plan politique mais cela valait la peine de montrer comment on pourrait trouver un nouvel équilibre dans ce domaine qui nous est si cher de la propriété intellectuelle.

Mais ce n'est pas tout : tu m'as invité à donner, à l'occasion de mes visites à Stockholm pour le projet IPT, un cours annuel sur les conventions internationales dans le domaine de la propriété industrielle dans le cadre du « Master programme » que tu avais créé à l'Université de Stockholm. Ce fut aussi, pendant 7 ans, une expérience passionnante car les étudiants que j'ai côtoyés à cette occasion venaient en majorité des pays nordiques et de l'Europe de l'Est, un public très différent de ceux que je rencontrais dans les autres universités en Europe où j'ai eu l'occasion de donner des cours à la même époque.

Voilà les raisons qui ont provoqué en moi un profond sentiment de reconnaissance à ton égard pour m'avoir offert des activités très enrichissantes sur le plan intellectuel et des occasions de rencontres tout autant enrichissantes sur le plan humain. Le temps passe mais l'amitié reste !

Ancien Vice-directeur général de l'Organisation Mondiale de la Propriété Intellectuelle  
Ancien Professeur associé au Centre d'Etudes Internationales de la Propriété Intellectuelle  
Former Deputy Director General of the World Intellectual Property Organization  
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### François Curchod

François Curchod is Doctor of Law of the University of Lausanne (Switzerland). He spent most of his professional life at the World Intellectual Property Organization (WIPO) and was a Deputy Director General of WIPO from 1991 to 2001. He has been an Adjunct Professor at the Robert Schuman University of Strasbourg (France) from 2001 to 2008, teaching mainly international conventions in the field of intellectual

property. He also gave courses at various other Universities. He is presently "chargé de mission" for the Centre for International Intellectual Property Studies, CEIPI, which he represents at WIPO meetings.

# Looking up substance and procedure via alternative DNS providers: the tale of injunctions to enforce copyright

By Prof. Dr. Paul L.C. Torremans

## INTRODUCTION

The request to contribute to an issue to celebrate the work of Marianne Levin brought back plenty of nice memories. I had the pleasure of knowing Marianne for many years and I remember with pleasure those sessions I taught in Stockholm with Marianne and her dog in the back of the room. And when they took place on a Saturday her father would come along too and on a couple of occasions we ended up lunching on pizza at Pic-Nic on campus. Later on, we did our EU funded project on human embryonic stem cells and on one occasion Marianne chaired a meeting from campus whilst I was stuck on a plane that had diverted to Gothenburg because the radar at Arlanda Airport had gone down. With the doors of the plane open I could join the meeting via mobile and when I finally hurried in by taxi from Bromma Airport the draft we had been discussing was all ready and merely needed proofreading.

Leaving those memories to one side I asked myself what kind of topic I should pick for a contribution. In the end I decided not to risk a topic in a area where Marianne is the real expert and I decided to stick to my own hunting ground of private international law and intellectual property. Injunctions are a necessary tool when it comes to the enforcement of intellectual property rights on the internet, but the question arises, not just which judge has jurisdiction to award them, but in the context of preliminary injunctions when speed is of the essence the question of applicable law is crucial. Which law will a judge apply when issuing a preliminary injunction that covers several jurisdictions? I want to explore in particular the distinction between substantial and procedural law in this area. And I will do so against the background of the use of alternative DNS servers and providers. That is after all a typical scenario where rightholders in the music and movie industry feel they really need cross border injunctions when they try to enforce their copyright.

## ALTERNATIVE DNS SERVICE PROVIDERS AND ALTERNATIVE DNS SERVERS

Your internet service provider will provide you with a DNS server, or more precisely with the use of a DNS server. This is an essential tool if you want to access the internet and find domains and information on it, as computers, or

for that purpose any other device one connects to the internet with, know nothing about domain names. They are therefore not able to follow up on your search request and they cannot connect to a domain or search for it. On the other hand, the internet works on the basis of IP addresses, and that's what your computer or browser connects to when you point it somewhere. The essential element that is needed in this constellation is a link between IP addresses and domain names. And this is where the DNS server comes in. The DNS server will link domain names to IP addresses. In short, when you type any domain into your browser's address bar, the browser first goes to a DNS server. The server tells your browser the IP address that is associated with the requested domain name. Then it uses that IP address to connect you.<sup>1</sup>

The DNS server plays the role of the yellow pages on the internet. Names and domain names are important, but in the interests of communication you need the IP address associated with them. It is that link that your system looks up in the DNS server. All this is relatively uncontroversial. But there are plenty of offers to use an alternative DNS server around and these seem to upset copyright owners in the movie and music industries.

What do we mean when we refer to an alternative DNS server? What use is there in changing the DNS server you use and depart from the one offered to you by your internet service provider? The straightforward answer is that some yellow pages are better than others. Alternative DNS servers may allow you to find and use more pages and domains on the internet. An alternative DNS server may provide you with a better service. Some alternative DNS server also provide much higher speeds than the ones provided by internet service providers. That may be particularly attractive to the users in the gaming sector, where speed and volume of data are crucial factors.<sup>2</sup> In essence, all of these are perfectly good reasons to opt for the services of an alternative DNS service provider, with negligible risks in terms of potential copyright infringement.

A different DNS server can, however, also help you unblock geo-restricted content. Access to geo-restricted content becomes an option if you use a DNS server in the territory to which access is restricted or if the DNS server misleads the target domain into thinking you come from the authorised territory by interposing itself between your computer or device and the domain and its hosting server. Here we touch upon another important reason for

which people use alternative DNS servers. Alternative DNS servers are indeed also very good tools to protect the internet user's privacy. By interposing an alternative DNS server it becomes possible to keep one's own IP address private, or at least that is a service option that is offered by many alternative DNS servers and providers. And the user's own internet service provider cannot monitor his or her activities on the internet closely as in order to do so they need the data from their own DNS server, which you do not use. And they have no access to the data, nor do they exercise any control over the alternative DNS service provider. Alternative DNS providers that cherish privacy also often adopt a policy to delete logs of a user's activity very frequently.<sup>3</sup>

That is, of course, where the problem comes in for copyright enforcement on the internet. This privacy option makes the use of alternative DNS providers a very attractive option for any person who wants to share or stream music and film on the internet without obtaining copyright permission. Music, record and movie companies and rightholders find it very difficult to enforce their rights. They primarily want to target the primary infringers who share or stream the files containing the protected copyright material, but they find it impossible to ascertain their identity if they use alternative DNS servers. One can detect the fact that these files are circulating, but the trail towards the identity of the internet user who is responsible for this infringing activity ends in the dead end of the privacy policies of the alternative DNS providers. And the internet service providers do not have access to the data either, as their DNS servers are not used by those involved. That means that an injunction against the internet service provider obliging that company to block access to a certain website from which the illegal files originate becomes useless, as the internet service provider is not used to gain such access and they have therefore no trace of the illegal activity. So, they cannot take action to stop or hinder the infringement.

Hence the need for the rightholders to seek injunctive relief against the alternative DNS providers. They have the data of the traffic and can track any activity to and from sites that facilitate copyright infringement by hosting or streaming infringing copies of copyright protected

materials. They know the identity of their clients. In short, they are able to stop the infringing activity and they can be asked to identify their clients who allegedly infringe copyright in the works involved. Alternative DNS providers typically deploy their activities at a global level though. That makes national injunctions less useful. We will nevertheless look at the option of national injunctive relief against alternative DNS providers. However, the really useful tool would be a single injunction against alternative DNS providers, but then an injunction with a global scope of application. That will be the final target that we examine in this article. We will look at these questions from a European perspective.

## JURISDICTION: A PRIMER

I do not have the intention to go into any detail concerning jurisdiction. Suffice it here to say that in terms of jurisdiction one needs a single anchor for an injunction case to be able to be brought successfully. Article 4 and Article 7(2) Brussels I Regulation<sup>4</sup> can provide that, but the latter only in the courts of the place where the act leading to the damage takes place. The Brussels I Regulation is however restricted to defendants that are domiciled in the jurisdiction. For defendants domiciled in a third country reliance will have to be placed on the national private international law rules on jurisdiction of the member state where the claimant wishes to bring the case. For our current circumstances the article 4 judge of the domicile of the defendant will have jurisdiction over the whole case that is brought against the defendant, irrespective of the various jurisdictions in which the infringing activities take place. That jurisdiction brings also with it the issue of a preliminary injunction, at the very least for each jurisdiction whose substantive intellectual property law the judge will apply.<sup>5</sup> In a territorial system that means that the judge has accepted his or her jurisdiction over the activities of the defendant in that territory and hence the option not merely to determine whether or not an infringement took place under the local applicable law, but also the option to award a remedy, here an interim or preliminary injunction.<sup>6</sup> Article 7(2), first limb, offers a similar kind of jurisdiction to the judge of the place of the

<sup>1</sup> [https://en.wikipedia.org/wiki/Alternative\\_DNS\\_root](https://en.wikipedia.org/wiki/Alternative_DNS_root).

<sup>2</sup> See e.g., [https://www.cloudflare.com/en-gb/dns/?&\\_bt=526973815365&\\_bk=cloudflare%20dns&\\_bm=e&\\_bn=g&\\_bg=128351482488&\\_placement=&\\_target=&\\_loc=9056328&\\_dv=c&awsearchcp-c=1&gclid=EAlalQobChMl7aXdga\\_f9wIVlQU-GAB0wng0LEAAYAiAAEgLZd\\_D\\_BwE&gclid=aw.ds](https://www.cloudflare.com/en-gb/dns/?&_bt=526973815365&_bk=cloudflare%20dns&_bm=e&_bn=g&_bg=128351482488&_placement=&_target=&_loc=9056328&_dv=c&awsearchcp-c=1&gclid=EAlalQobChMl7aXdga_f9wIVlQU-GAB0wng0LEAAYAiAAEgLZd_D_BwE&gclid=aw.ds).

<sup>3</sup> <https://privacysavvy.com/security/business/best-free-public-dns-servers/>.

<sup>4</sup> 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 [2012] OJ L 351/1.

<sup>5</sup> Article 2:604 Principles for Conflict of Laws in Intellectual Property, European Max

Planck Group on *Conflict of Laws in Intellectual Property, Conflict of Laws in Intellectual Property: The CLIP Principles and Commentary*, Oxford University Press (2013) and the commentary at pp. 180-185.

<sup>6</sup> J.J. Fawcett and P. Torremans, *Intellectual Property and Private International Law*, Oxford University Press (2nd ed, 2011), Ch. 5.

allegedly infringing act leading to the damage took place. Once again that leads to jurisdiction to issue a preliminary or interim injunction.<sup>7</sup>

If we apply that to the providers of alternative DNS servers the judge of their domicile or place of the establishment in the European Union will have jurisdiction, as will the judge of the place from where the allegedly infringing service is provided, i.e., the place of the servers whose operation enables the clients to access, stream or download the infringing material. This is in essence a reference to the relevant data centre for this activity deployed by the provider of the alternative DNS server.

## CHOICE OF LAW

On the assumption that a court of competent jurisdiction has been identified and that the case is pending before that court one moves on to choice of law and one needs to determine the applicable law. It may be slightly misleading to rely here too much on the recent cases in relation to harmful statements/defamation<sup>8</sup> and personal data<sup>9</sup>, as these areas of law are rather different from intellectual property in general and copyright in particular. Case C-18/18<sup>10</sup> also does not contain any discussion of the choice of law problem. The case seems to assume that the statements will be harmful anywhere in the world, but this is due to the mechanism of references to the Court of Justice of the European Union. The referring court had already made a finding that the statements amount to defamation or were 'illegally harmful' one way or another under the applicable law (or laws). The Court of Justice of the European Union was asked to take that as a given and merely explain Directive 2000/31/EC and the potential for an injunction with a global scope. Be that as it may, the applicable law issue is crucial for the question whether a

worldwide or EU-wide injunction can be granted. As AG Szpunar notes at paragraph 86 of his opinion in case C-18/18 *Eva Glawischnig-Piesczek v. Facebook Ireland Limited*, a court may be prevented from granting or authorising to grant a worldwide injunction not because of its jurisdiction (which under articles 4 and 7(2) place of the act is by definition global in scope), but because of a matter of substance and therefore of applicable law.

Territoriality is and remains the guiding principle when it comes to copyright choice of law. This means that the choice of law rule will lead to the application on a country by country basis of the local copyright law. Or to the application of the *lex loci protectionis* or the law of the country for which protection is sought. This means that French law will be applicable to any copyright claim concerning France, German law to any copyright claim concerning Germany, etc. This rule applies even if copyright protection is claimed in a number of countries and leads to the application of a patchwork of national laws in a single case even if the copyright and the alleged infringement are virtually identical. In an infringement context this rule is also laid down in article 8 of the Rome II Regulation.<sup>12</sup>

As a competent court (in the European Union) will necessarily apply its own choice of law rules as part of the law of the forum that applies to procedural issues, such a court will apply the *lex loci protectionis* choice of law rule to the whole case in front of it, including the alleged infringement in third countries.

An injunction is one way or another a remedy that is linked to a finding of infringement, even if the injunction is issued against an intermediary. And as copyright is, just as any other intellectual property right, essentially a negative right to stop other parties from doing certain things without authorisation (reproducing the work, communi-

cating the work to the public, etc ...) and as copyright is a private right remedies are an essential component when it comes to enforcing the right through infringement proceedings. It is therefore logically and globally accepted that the remedies, and therefore also our injunction, are governed by the *lex loci protectionis*.<sup>13</sup> It is worth reminding ourselves on this point that whilst article 8(3) of the Information Society Directive puts in place an obligation to make injunctive relief available, it leaves the details to the national laws that implement the directive. These national laws may stipulate (or limit) the territorial scope of such an injunction<sup>14</sup>, but they rarely do. In any case one will merely apply these laws to impose an injunction in a single country, on a country by country basis. And the Court of Justice has added that there is nothing in EU law that prohibits the issuing of a worldwide injunction by a court of a member state.<sup>15</sup> In relation to third countries to court will apply to local law of those countries, which may know such an injunction and which may have a scope provision.

One is therefore left with a country by country, national law by national law, patchwork and the burden of proof that goes with it. In terms of the (territorial) scope of the injunction the CLIP group, of which this author is a member, arrived at the conclusion that an injunction issued by a court of competent jurisdiction shall only concern activities affecting intellectual property rights protected under the national law or laws applied by the court.<sup>16</sup> Cumbersome as it may be, it also eliminates any comity of nations concerns that may arise in the context of a global injunction from a public international law point of view. This is by the way not a 'radically new' academic proposal. It is reflected in the current practice of those courts<sup>17</sup> that have accepted that they can deal with foreign copyright.<sup>18</sup> Courts have also refused to grant an injunction for those jurisdictions where there would not be an infringement of the intellectual property right concerned, which points towards the application of the rule set out here. A global, but perhaps more realistically and EU-wide injunction is therefore possible on this basis. The latter is also facilitated (in terms of burden of proof) by the relative level of copyright harmonisation in the European Union. But one also needs to draw a delicate distinction here between substance and procedure and it is to this point that we now turn.

## The qualification question

In relation to injunctive relief granted as an interim measure the question arises whether, before granting an injunction in relation to alleged copyright infringement, the judge should check whether the conditions for imposing such a measure in interlocutory proceedings are met in each of the legal systems potentially concerned. In this respect, it is of fundamental importance to correctly qualify the question in private international law. With regard to infringement of intellectual property rights, there is a delicate distinction between a procedural and a substantive classification.

## The substantive classification in the Rome II Regulation

Infringements of intellectual property rights fall within the scope of the Rome II Regulation. It is sufficient to refer in this respect to the specific rule in Article 8 of the Regulation and the *lex loci protectionis* rule contained therein. On questions that are qualified as questions of substantive law, the *local lex loci protectionis* will therefore have to be applied on a territorial basis country by country. The classification as a question of substantive law is then determined by Article 15 of the Rome II Regulation. This is clear from the heading 'scope of applicable law'.

Article 15 of the Regulation requires the application of the *lex loci protectionis* to the question of what constitutes an infringement of copyright law, since for copyright this concerns the ground and extent of liability to which article 15(a) refers. Paragraph (b) logically supplements this with the applicability of the *lex loci protectionis* on the grounds for exclusion of liability. With regard to intellectual property rights, the exceptions not only constitute grounds for expression or limitation of liability, but also determine the precise scope of protection and therefore also the precise scope of liability for an (alleged) infringement.

Intellectual property rights are essentially negative rights, since the exclusive right they confer allows the owner of the right to prohibit anyone who does so without his consent from engaging in restricted acts such as copying the work or communicating it to the public. This means that, for intellectual property law, there is a very close link between the scope of the right, the infringement of the right and the enforceability of the right. In the case of private international law, this translates into the same qualification and the application of the *lex loci protectionis*. Enforceability therefore also falls within the scope of the substantive classification. Article 15 of the Rome II Regulation takes the same approach and paragraph (c) assumes that the existence and nature of the

<sup>7</sup> Case 21-76 *Handelskwekerij G.J. Bier BV v. Mines de Potasse d'Alsace SA* ECLI:EU:C:1976:166; Case C-68/93 *Fiona Shevill, Ixora Trading Inc., Chequepoint SARL and Chequepoint International Ltd v. Presse Alliance SA* ECLI:EU:C:1995:61; Case C-228/11 *Melzer v. MF Global UK Ltd* ECLI:EU:C:2013:305; Case C-387/12 *Hi Hotel HCF SARL v. Uwe Spoering* ECLI:EU:C:2014:215; Case C-360/12 *Coty Germany GmbH, formerly Coty Prestige Lancaster Group GmbH v. First Note Perfumes NV* ECLI:EU:C:2014:1318; Case C-170/12 *Peter Pinckney v. KDG Mediateg AG* ECLI:EU:C:2013:635 and Case C-441/13 *Hejduk v. EnergieAgentur* ECLI:EU:C:2015:28.

<sup>8</sup> Case C-18/18 *Eva Glawischnig-Piesczek v. Facebook Ireland Limited* ECLI:EU:C:2019:821.

<sup>9</sup> Case C-507/17 *Google LLC, successor in law to Google Inc. v. Commission nationale de l'informatique et des libertés (CNIL)* ECLI:EU:C:2019:772.

<sup>10</sup> Case C-18/18 *Eva Glawischnig-Piesczek v.*

*Facebook Ireland Limited* ECLI:EU:C:2019:821.

<sup>11</sup> Case C-18/18 *Eva Glawischnig-Piesczek v. Facebook Ireland Limited* ECLI:EU:C:2019:821, Opinion of AG Szpunar ECLI:EU:C:2019:458.

<sup>12</sup> 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) [2007] OJ L 199/40.

<sup>13</sup> See Article 3:601 Principles for Conflict of Laws in Intellectual Property, European Max Planck Group on Conflict of Laws in Intellectual Property, *Conflict of Laws in Intellectual Property: The CLIP Principles and Commentary*, Oxford University Press [2013].

<sup>14</sup> Case C-18/18 *Eva Glawischnig-Piesczek v. Facebook Ireland Limited* ECLI:EU:C:2019:821, Opinion of AG Szpunar ECLI:EU:C:2019:458, at paragraph 92.

<sup>15</sup> Case C-18/18 *Eva Glawischnig-Piesczek v. Facebook Ireland Limited* ECLI:EU:C:2019:821.

<sup>16</sup> Article 2:604 Principles for Conflict of Laws in Intellectual Property, European Max Planck Group on Conflict of Laws in Intellectual Property, *Conflict of Laws in Intellectual Property: The CLIP Principles and Commentary*, Oxford University Press [2013] and the commentary at pp. 180-185.

<sup>17</sup> See Alexander Peukert, 'Territoriality and Extraterritoriality in Intellectual Property Law' in Günther Handl, Joachim Zekoll & Peer Zumbansen (eds), *Beyond Territoriality: Transnational Legal Authority in an Age of Globalization*, Queen Mary Studies in International Law, Brill Academic Publishing [2012] 189 and Marketa Trimble, 'Extraterritorial Intellectual Property Enforcement in the European Union', [2011] SW J Int'l L 233.

<sup>18</sup> See the debate in *Lucasfilm Limited and others (Appellants) v. Ainsworth and another (Respondents)* [2011] UKSC 39 [Supreme Court, United Kingdom].

<sup>19</sup> *Playboy Enters v. Chuckleberry Publ'g Inc, 939 F Supp 1032 (SDNY 1996)*, *Sterling Drug Inc v. Bayer*, 14 F 3d 733 [2d Cir 1994].

damage or the claim are determined on the basis of the *lex loci protectionis*. It is important not to lose sight of the fact that the Regulation also adds the estimate of the damage or the claimed. All this is part of one package, certainly with regard to intellectual property rights. But one must put paragraph (c) in context as a logical continuation of paragraphs (a) and (b). On the basis of paragraphs (a) and (b), a ground of liability and its extent shall be determined with due regard for any limitations and exceptions. Paragraph (c) then takes the logical next step and subjects the further requirement to successfully complete the infringement claim to the same applicable law. Damage is a requirement and the applicable law then determines whether or not there is damage, what nature the damage must assume and how that damage must be estimated. That last point was regulated differently in English law for the Rome II Regulation and it is in this context that the comments of Plender and Wilderspin should be read. They also exclude the application of paragraph (c) to 'injunctive relief'. Or as Pontier aptly summed it up, 'in particular, this is about the question of what damages compensation can be obtained...' and, of course, the possible budgeting of that damage. Paragraph (c), on the other hand, makes no reference to the procedure to be followed by the competent court in this matter. It is merely a question of the scope of the substantively applicable law, which is logical since the regulation indicates in its name that it is merely a regulation 'concerning the law applicable to non-contractual obligations'. It is only about the (substantive) obligation.

Paragraph d) further adds in connection with the enforceability. Therefore, the measures that the court can take to prevent, limit or have compensation for injury or damage are also governed by the *lex loci protectionis*. The remedies, and more specifically the answer to the question of which remedies are available, therefore fall within the scope of the *lex loci protectionis* and are given a substantive classification in the Rome II Regulation. One thinks more specifically of the possibility of compensation, but also of the availability of a (cross-border) ban (injunction). However, the commentators agree that paragraph (d) refers solely to the availability of a particular remedy! Only then does it make sense, as the text of paragraph (d) does, to subject the effective application of a remedy under the applicable law and the relevant *lex loci*

*protectionis* to the restriction that this must be possible within the limits of the court's procedural jurisdiction. If there is nothing left that deserves a procedural qualification, this phrase in paragraph (d) is taken away from every sentence. One must therefore assume with Pontier that the judge 'is not obliged to take measures that are not known to its own procedural law'. In addition to the substantively qualified provisions on availability, there is therefore scope for a procedural classification and the application of the law of the court on the procedure to be followed in the application of the available remedies. This is difficult if the law of the court does not provide for such a remedy and therefore paragraph (d) contains the restriction that in that scenario the court is not obliged to apply the remedy of the *lex loci protectionis* unknown in its law.

### Complementary and unavoidable procedural qualification

However, with regard to patent infringements and the potential for (cross-border) prohibitions, this is the limit of the scope of the applicable law as laid down in Article 15 of the Rome II Regulation. This is where the substantive classification for the purposes of private international law stops. In addition, there is therefore a very clear place for a number of questions that will be classified in procedural law and to which the *lex fori* or the law of the court will be applied. Traditionally, one thinks here not only of the way in which the court conducts its proceedings, in cases concerning non-contractual liability, but also of the rules on the taking of evidence. More specifically, the *lex fori* applies to the procedure or procedures available to the patent owner to request the court to grant the remedies (which are available under substantive law/*lex loci protectionis*). The court will therefore apply the *lex fori* and therefore its own procedural law in the handling of that application. It is therefore, for example, the *lex fori* which determines, among other things, whether, and under what conditions, a short or accelerated procedure, such as summary proceedings, can be used to grant those remedies (determined by substantive law). Article 15 refers to this by stating that work is carried out within a procedural law framework, in other words certain aspects do have a procedural classification, and that procedural framework is that of the court, and therefore of the *lex fori*.

This application of the *lex fori* under a procedural classification has also been adopted in several judicial decisions. The Court of Appeal of England and Wales followed this approach in *Gerard and Daniela Maher v. Groupama Grand Est*. More recently, that was also the case in the decision of the *Supreme Court of the United Kingdom in Actavis UK Ltd v. Eli Lilly and Co*. This case concerned patent infringements in the United Kingdom, France, Italy and Spain and the Supreme Court upheld the handling of the case as set out by Arnold J. at first instance. On the substantive law aspect, or in practice the question of whether there was an infringement of the patent (and the available sanctions and the budget of the damages), the *lex loci protectionis* was applied country by country, but to the entire procedure, including the taking of evidence,

the conditions for granting a remedy and the way in which the court arrives at the finding of an infringement and the granting of a remedy, English law as the *lex fori* was applied without any hesitation. There is also the Opinion of Advocate General Szpunar in Case C-18/18 *Eva Glawischnig-Piesczek v. Facebook Ireland Limited*, which makes a very clear distinction between questions of substantive jurisdiction and questions of procedural classification. The Advocate General agrees with the referring Austrian court that there is a tort in any applicable substantive law and asks whether in certain scenarios a single law can apply if the case has a worldwide scope (that can now be disregarded here and the Advocate General does not answer that either since that was not necessary in this case), but he refers, after having established that the European rules of jurisdiction do not preclude this, the question of whether and how a cross-border order can be issued to the Austrian courts and procedural law. The Court of Justice followed the opinion of its First Advocate General in the judgment, without going into further detail on this point.

The procedural qualification and the application of the *lex fori* to these questions is also the translation of the sociological need for an efficient legal system and procedure to resolve disputes between civil parties. In the same vein, Vlas's suggestion of flexibility in the interlocutory procedure with a (broad) application of the *lex fori* should also be seen. However, the basic rules of applicable law apply both to the main proceedings and to proceedings for interim measures, with the division described above between the *lex loci protectionis* as applicable law to questions which are classified substantively and the *lex fori* as applicable law to questions classified in procedural law.

Summing up on this point, the judge hearing the application for a cross-border prohibition must determine for each country whether the *lex loci protectionis* recognises the existence of an injunction. The answer to this question is fairly simple within the European Union, since Article 9 of the Enforcement Directive expressly provides for such a remedy as a typical example of the provisional and precautionary measures provided for there.

The procedural classification of the question of which procedure or procedures are available to the copyright owner to request the court to grant the existing remedies and of the question of which procedural rules the court will follow in the handling and assessment of such an application leads to the application of the *lex fori* to these questions (and to other procedural aspects). In the copyright infringement context of the interlocutory proceedings, it is then, among other things, specifically about the conditions for imposing a prohibition. It is therefore the *lex fori* that determines whether there must be an urgent interest and, if so, what that should entail. It is the *lex fori* that determines whether and under what conditions and in what way there is a need for a guarantee. In this case there is no room for any application of the *lex loci protectionis*.

## CONCLUSION

The picture that emerges remains a complex one, involving the application of several national laws. But the fact that the competent judge can apply a single applicable law to the procedural aspects of issuing a preliminary or interim injunction and the fact that that will be the law of the judge will allow the judge to proceed smoothly and swiftly.

The rightsholder will therefore be able to seek a multi-territorial injunction against an alternative DNS server provider. In terms of whether an injunction as a *tup* of remedy is available we are back to substantive law and there one has to rely of the country by country application of the national intellectual property law. Territoriality is on this point still the rule. But that provides an important safeguard for the defendant and alleged infringer. Intellectual property rights are negative rights to stop others from doing certain things and there is therefore an unbreakable link between (alleged) infringement and remedies. It is therefore logical and an important safeguard that the same law applies to substantive copyright law, i.e., the infringement issue, and the remedy, i.e., the preliminary or interim infringement issue. The way forward here is essentially found in legal harmonisation, both in terms of substantive intellectual property law and in terms of remedies and enforcement.



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# Training of copyright and related rights in sub-saharan Africa

## A Case Study on Collective Management in Today's Reality

By Tarja Koskinen-Olsson, International Adviser

### INTRODUCTION

Training of intellectual property rights has been close to the heart of Professor Marianne Levin and she has been a Master Trainer, welcoming participants from all corners of the world. This is why I have chosen the topic of training for my article, congratulating her on her anniversary.

Understanding how international copyright law and realities on the ground affect the functioning of the copyright market in a given country or region, offers a possibility to review and evaluate developments.

A well-functioning copyright market consists of three elements: legislation, enforcement and management of copyright and related rights. This article concentrates on management of rights, but deals also with some legislative and enforcement issues.

Management of rights takes place either individually by the respective rightsholder or by collective management organizations (CMOs). The latter is a feasible solution when individual exercise of rights is either impossible or impracticable.

### BACKGROUND

This article is based primarily on the findings of a training session on collective management held in Nairobi, Kenya, in May 2022. The training was preceded by an intensive online session in November 2021. As the result of the online training each participant had chosen some development targets and key performance indicators (KPIs) to measure their fulfillment. This method of training points out to two pertinent issues that I consider as important:

- The hybrid training model is here to stay.
- Any training activity needs to define its goals and measurable results.

Participants from thirteen countries (Botswana, Burkina Faso, Cameroon, Ghana, Kenya, Malawi, Mauritius, Nigeria, Sierra Leone, South Africa, Uganda, Zambia and Zimbabwe) participated at this MasterClass training organized by the Norwegian Copyright Development Association (NORCODE), in cooperation with The African Regional Intellectual Property Organization (ARIPO), International Federation of Reproduction Rights Organi-

sations (IFRRO), The International Confederation of Societies of Authors and Composers (CISAC), The International Federation of the Phonographic Industry (IFPI) and The Societies' Council for the Collective Management of Performers' Rights (SCAPR).

The article also reflects previous developments in the region, based on my 20 years of involvement in training in the region.

### HISTORY OF COLLECTIVE MANAGEMENT IN THE SUB-SAHARAN AFRICA

Collective management is common in all sectors of the creative industry. The first organization was established in France as early as in 1777 to defend playwrights in their fight to get paid for their plays in theatres. The first collective management organization for rights in musical works was established in 1852 also in France. STIM in Sweden was founded in 1923, and thus celebrates its 100<sup>th</sup> anniversary in 2023. European organizations can thus draw the benefits of a long history and experiences gained in the ever-changing technological environment.

In Sub-Saharan Africa, the first organization emerged in 1961 in South Africa when The Southern African Music Rights Organisation (SAMRO) was established. Many more organizations were established in early 1980s. For instance, Zimbabwe Music Rights Association (ZIMURA) was established in 1982. It is a small miracle that this organization has survived and developed during all the political and economic tumult in the country.

To take another creative sector, print and publishing, the first collective management organizations emerged in 1970s when widespread photocopying started. As it would not be feasible for educators to seek permissions for photocopying extracts of publications from all over the world, collective management was found to offer services to both rightsholders and users of copyrighted works.

In Sub-Saharan Africa, the first organization was again in South Africa, where Dramatic, Artistic and Literary Rights Organization (DALRO) was established in 1967. It functions as a multi-purpose CMO for dramatic, artistic and literary rightsholders. Later on, it started also to license photocopying.

Sweden was the first country where a Reproduction Rights Organization (RRO), called today BONUS Copy-

right Access, was established by authors and publishers in 1973, soon to be followed by similar organizations in neighboring countries. Different creative sectors have chosen to call their organizations by different names, the one in the text and image sector being an RRO. The Reprographic Rights Organization of Ghana (Copy-Ghana) was established in 2011 and it is an example of an RRO in the region that has managed to license educational institutions for their wide-spread copying. Successful litigation against a major university recently segmented the need to acquire permission from authors, visual creators and publishers through the services of CopyGhana.

These two examples offer a glimpse to the birth histories of collective management organizations in the world and in the Sub-Saharan region.

### DIFFERENT TYPES OF CMOs IN THE REGION

In general, CMOs have two common characteristics:

- a) They are private organizations, established by rightsholders
- b) They are not-for-profit organizations.

In Sub-Saharan Africa, the status and legal nature of a CMO varies greatly, the main categories being:

- Governmental organizations, working as a branch of the relevant authority;
- Combination of a Copyright Office (as regulator) and a CMO
- Private multi-repertoire organizations
- Private organizations for a given group of rightsholders or rights.

Governmental organizations are common in Francophone Africa. In the case of Burkina Faso, for example, Bureau Burkinabe Du Droit d'Auteur (BBDA) was established in 1985 as a multipurpose CMO for all groups of rightsholders. The salaries of the staff, altogether 96 persons, are paid by the Government, in the same way as in other governmental branches. The major source of income comes from remuneration for private copying; an issue that I will describe separately.

Malawi offers an example of an organization which combines the Copyright Office (as the regulator is called in this text) and that of the CMO. The Copyright Society of Malawi (COSOMA) was established in 1992. This legal structure is currently under review and there is a possibility that the two tasks will be separated and as a consequence, COSOMA maybe continues as a CMO. This remains to be seen.

The Copyright Society of Botswana (COSBOTS) was established in 2008 as a multi-repertoire CMO. Due to a favorable legal structure and comparatively high GDP/capita, the collection of COSBOTS has been successful. Whereas the organization in practice started with management of rights in musical works, it has now expanded to reprography and looks forward to management of rights in audiovisual works.

Kenya offers an example that most resembles the structure in Sweden. The Music Society of Kenya (MCSK) is the oldest CMO which started in 1983. Later the management of rights in sound recordings became actual and two new CMOs were established for performers and music producers respectively. Performers Rights Society of Kenya (PRISK) and Kenya Association of Music Producers (KAMP) started functioning towards the end of 2000. It was not easy to explain for music users that they need three separate licenses to play music. As a consequence, all three CMOs founded a strategic partnership for joint licensing of background music, supported by the relevant ministry. The Kenyan structure has many similarities with the Swedish system with STIM, SAMI and IFPI, the two latter issuing joint licenses under agreed conditions.

The not-for-profit feature of collective management is valid in practically all CMOs in the region. It has in some cases been difficult for the regulator to understand the role of collective management. In best cases, they deal with a lot of revenue, but they are still not-for-profit. The revenue that a CMO collects for the use of its members' works is, however, not the money of the CMO. It only holds the money in trust before distributing it to the rightsholders. This feature is one of the reasons for necessary regulatory framework for collective management.





A more coherent regulatory framework for collective management, including the relationship between the regulator and the CMOs, would be a useful tool in many countries in the region.

### GOOD GOVERNANCE OF CMOs

The single most important success factor in the work of any CMO is good governance. It is unfortunately also the number one reason for failure. Examples of poor governance have been experienced on all continents.

The main elements of good governance are the following:

- Clear governance structures
- Transparency
- Accountability

A solid governance structure ensures that there is clear separation of powers and role clarity between the Board and the management. The main principle is that the Board Chair leads the Board and the Chief Executive Officer (CEO) leads the management. Both the Board and the management have a common goal to serve the rightsholders in the best possible manner, but they have separate roles and responsibilities. The main tasks of the Board are the following:

- Strategic leadership
- Advisory role vis-à-vis the CEO
- Supervision of the activities

All too often do members of the Board and the Board Chair get involved in day-to-day managerial questions, instead of discussing strategic issues that have an effect in the longer run. There are also cases where a strong CEO imposes his/her decisions and the Board becomes a mere stamp. However, in the Sub-Saharan context there are more cases where the Board and in particular the Chair decides all details, acting as a dictator. The goal in the interaction between the Board and the management is strategic partnership.

Transparency and accountability go hand in hand, and it is difficult to be accountable without being transparent. Most CMOs need to provide audited accounts to the regulator, but transparency means a lot more than just posting the official documents on the webpage of the organization. In the European Union, CMOs need to publish yearly a fairly detailed transparency report and that might serve as a useful tool also for CMOs on other continents.

Accountability calls for actions. The organization needs to explain why certain measures have been taken and give justification for them. Accountability is particularly important in crisis situations, when things have gone wrong. Speedy action and explanation go a long way instead of trying to hide the failure and reasons thereof. This is equally true for all CMOs, irrespective of the continent.

The recent training in Nairobi stated in its Call for Action that training is needed on good governance, including the business of collective management. Board mem-

bers need to understand that the core business of a CMO is rights management. They handle other peoples' rights and money. There is a money-in (licensing and collection) element and a money-out (distribution) element in every CMO. The only true measure for success of a CMO is distribution of revenue to rightsholders.

### COMMUNICATION AND REPUTATION MANAGEMENT

Communicating in an understandable and clear manner to all stakeholders plays a key role in collective management. Long gone are the days when experts could satisfy their audience by saying that "copyright is a very difficult and complicated field of law", indicating that only the experts are capable of understanding the implications. There might be complicated issues involved in collective management, but they need to be communicated so that an ordinary human being can understand it. This is in many cases more difficult than using the jargon of the professionals.

The reputation of collective management organizations is not sufficient in many countries, and Sub-Saharan Africa is no exception in this regard. That is why building a reputation management plan as part of the communication strategy, planning and policies is important. The financial guru Warren Buffet has stated: "Building a good reputation takes 20 years, but it can be ruined in five minutes". This is a message to all organizations, including CMOs. One cannot build a reputation on what an organization is going to do; reputation is built always on real actions on the ground.

Too often, unfortunately, emerging CMOs in the region suffer from rivalry and conflicting interests of different rightsholder groups, instead of solidarity and common action. In the field of music, for instance, elections for the Board have not always been held regularly. If the organization is not performing to the satisfaction of all its members, the first desire is to establish a second one; a solution that would create even more chaos in the marketplace. In such instances, it is clear that the reputation of the CMO suffers and it takes a long time to rebuild a good reputation again.

In the following sections, I will deal with sector-specific current issues and how they play out in Sub-Saharan Africa, as compared to other parts of the world. I will also describe some sources of revenue with could have a major impact on the sustainability of CMO operations.

### MANAGEMENT OF MUSIC RIGHTS IN THE DIGITAL ENVIRONMENT

The digital environment and in particular licensing of digital service providers (DSPs) has led to great changes in how collective management functions in the field of music. While musical works are still to a large extent licensed collectively, rights in sound recordings are managed individually by music producers, also on behalf of music performers. Streaming services being the primary business of music producers, with fewer or practically no

CDs being sold, the steaming market is the focus of producers.

Multi-territorial licensing of musical works is a demand of DSPs, such as Spotify and Deezer. They are primarily wishing to deal only with CMOs that can offer multi-territorial licenses from one source. This is also the case in Sub-Saharan Africa. CAPASSO, the organization that manages the reproduction or "mechanical rights" in musical works, has created a Digital Rights Platform and can offer Pan-African licensing. Based on collaboration and reciprocal agreements with music CMOs of the region, the organization can license to DSPs a wide repertoire. As African music is on high demand on the marketplace, CAPASSO plays an important role side-by-side with foreign providers of multi-territorial licenses and direct licensing by big music publishers. Competition in the marketplace is a fact.

A crucial issue in digital rights management is proper data management and availability of metadata. Collection of revenue from DSPs takes place on a work-by-work basis, meaning that each musical work must be identified before invoicing. This makes it necessary that all countries in the region which participate in multi-territorial licensing must be able to demonstrate appropriate data for each of their members' works. There is much to be done on the continent to reach the full potential. Each CMO in the region needs to handle its backyard and improve its technical infrastructure. Technical tools and worldwide identifiers exist and need to be applied throughout the continent.

As said at the outset, licensing of sound recordings for streaming purposes takes place individually by the music producers. Public performances of sound recordings are customarily managed by CMOs, called Music Licensing Companies (MLCs) by IFPI. Collective licensing revenue has grown in importance as a source of income for record labels in recent years and that is why investment in the collective management infrastructure also in Sub-Saharan Africa has increased during the last years. It is important that each CMO has adequate information of each market sector, for example the retail stores. Having such statistics, the CMO can define its current market share and set development targets for each year, including KPIs to measure achievements. This is of course valid for all CMOs, not only for MLCs in the sound recording sector.

### PRIVATE COPYING REMUNERATION

Private copying remuneration has proven to be a major source of income for the creative sector. It is important, therefore, to promote the implementation of private copying remuneration in all sectors in countries where such a system does not currently exist, or is not yet implemented.

It is important that the remuneration system is imbedded in copyright legislation, and preferably not called a levy on blank media. That refers to the market situation in the early stages. For instance, in Sweden the levy system was first introduced in 1999, the previous system being a tax-based solution. In Finland, the copyright levy was in-

### REGULATORY FRAMEWORK FOR COLLECTIVE MANAGEMENT

This is an area where the developments in Europe lag far behind what is customary in Sub-Saharan Africa. Almost all CMOs are regulated and provisions exist both in the copyright law itself and in implementing regulations.

The Collective Rights Management (CRM) Directive (2014/26/EU) offers nowadays a comprehensive legal framework for collective management in Europe, with designated regulatory bodies, like the Swedish Intellectual Property Office (PRV). Contrary to the rather late developments in Europe, the work of Sub-Saharan CMOs has in most countries been regulated since their establishment. Whereas the supervision is in most cases both necessary and beneficial, there are countries in the region where excessive interference by the regulator has led to the halt in activities. The longstanding wrangling between the Kenya Copyright Board (KECOBO) and the local CMOs has negatively affected the licensing landscape, leading to drastically decreased revenue to the rightsholders.

One of the key findings of the recent training which I use as the case study of this article is the following:

- Cooperation between the regulator and the CMOs is needed to achieve a conducive framework for collective management.
- There needs to be a clear separation of powers and roles between the Copyright Office and the CMOs. This leads to the best results for all stakeholders.

roduced already in 1984, as the fifth country in the world.

Most copyright laws in the world include an exception or limitation in the exclusive right of reproduction to copy for one's private use. This possibility is included in Article 9.2. of the Berne Convention. There are three criteria for any permissible exception, the so-called three-step-test. The third criteria "does not unreasonably prejudice the legitimate interests of the author" is the most important one in this context. The total amount of everybody's copying for private use is so huge that it easily prejudices the legitimate interests of rightsholders. For that reason, solutions for an indirect compensation have been sought, the first implementation being in 1965 in Germany. A small copyright fee is paid for all blank devices and media that can be used for private copying. Customarily the fee is paid by the importers or manufacturers and collected by one CMO, such as Copyswede in Sweden. The fee is passed on to the retail price and consumers end up paying the remuneration. They are also the beneficiaries of free private copying. For the system to survive, it needs to be updated together with technological developments.

The Information Society Directive of the EU (2001/29) introduced the requirement of fair compensation for private copying. It has thereafter been reinforced by judgements from the European Court of Justice and introduced in the majority of the EU Member States.

Without going deep into the legal debates, the implementation in Sub-Saharan Africa is the focus of my article. The system has been introduced relatively early in certain countries, such as Ghana and Burkina Faso. In both countries it has functioned well, but to do so also in the future, the list of devices and media need to be updated regularly. Recent implementation of the system in Malawi serves as an example of the great importance of the revenue for the sustainability of the copyright infrastructure.

There are some countries where the compensation system has been included in the law for a long time, but the implementing provisions are missing. Examples are Nigeria and Kenya, and in these countries rightsholders loose substantial revenue every year due to the non-implementation.

Common action plan for certain Francophone African countries has led to the introduction of a remuneration system for instance in Ivory Coast and Senegal. Regional implementation and action plans are called upon also for English-speaking countries.

## VISUAL ARTISTS' RE SALE RIGHT

Many countries in Sub-Saharan Africa have not yet adopted the resale right in their legislation. As there is a reciprocity requirement in the Berne Convention, countries without the relevant stipulations loose out in cases where works of art of their nationals are being sold in European countries.

For example, at Sotheby's bi-annual Modern and Contemporary African Art action in 2021, Nigerian artist Ben Enwonwu's sculpture "Atlas" was sold for USD 519,826. No resale remuneration was paid for this sale due to the

lack of legislation in the country of the artist. This is just one single example of the popularity of African artwork at the international art market.

Whereas the Directive (2001/84/EC) on resale right ensured implementation in Europe, there are still major art markets on other continents without legislation, examples being the United States and Japan. The obligation of resale right in all countries of the Union has been among the issues debated in the Standing Committee on Copyright and Related rights (SCCR) at the World Intellectual Property Organization (WIPO) since a few years now. It was first introduced by the Governments of Senegal and Congo.

## MANAGEMENT OF RIGHTS IN AUDIOVISUAL WORKS IN THE REGION

The Berne Convention leaves the question of authorship in audiovisual works for the national legislator to decide. This has also a bearing on how rights in audiovisual works are managed in different countries. Whereas the rights of authors in the digital environment were ensured and clarified by the WIPO Copyright Treaty (WCT) 1996, the legal position of audiovisual performers were left outside the scope of the WIPO Performances and Phonograms Treaty (WPPT). It took until 2012 when the Beijing Treaty on Audiovisual Performances (BTAP) became a reality. National implementation of the Beijing Treaty is a high priority in the region, and it can take place in such a form that it supports collective management of rights of audiovisual performers.

Contrary to many European CMOs in the audiovisual sector, there are joint CMOs in the region that manage the rights of all rightsholders, i.e., authors, actors and producers. Such organization exist in Ghana, Nigeria and Uganda. The assistance that international organizations render to their members tends to be sector-specific, making it difficult for joint organizations to implement all the different tools and programs. Greater collaboration is called upon by CISAC, SCAPR and International Federation of Film Producers Associations (FIAPF) respectively.

It may be an African specialty to have joint CMOs in the audiovisual sector, but it is firmly believed that the marketplace would not be supportive to different actions by authors, actors and film producers. Film business is an expensive undertaking and every film needs in the input of creative collaborators (authors and actors) and the financial input as resources from producers. It is interesting to note that measured by numbers of films produced yearly, Nigeria with its Nollywood is a leading market, followed by Bollywood in India and Hollywood in the US.

## MANAGEMENT OF RIGHTS IN THE TEXT AND IMAGE SECTOR

The COVID-19 pandemic has shown clearly that it is important to have quality educational materials available in both analogue and digital forms. Educational publishing is the motor of the publishing industry in many countries,

including Sub-Saharan countries. Therefore, the livelihood and working conditions of local writers and publishers should be high on the political agenda for creative industries.

On the contrary, many countries, including South Africa, have tried to push vast and unclearly defined exceptions and limitations to benefit educational institutions. While this may seem to be justifiable from a societal perspective, it would be detrimental to local authors and publishing.

Clear and precise legislative framework with exceptions and limitations, compliant with the three-step-test, as stipulated in the international treaties, is crucial in ensuring remuneration for rightsholders for mass uses of their works. The question of exceptions and limitations in education has for years now been on the political agenda for instance at the SCCR meetings of WIPO.

RROs in the text and image sector function in many countries in Sub-Saharan Africa, examples being Ghana and Zambia. Many multi-repertoire CMOs, such as COS-OMA in Malawi, have for years licensed the use of protected materials in higher education.

The importance of metadata, including the use of identifiers, needs to be fully recognized in the text and image sector, where RROs distribute collected revenue as title-specific remuneration to individual rightsholders, or plan to swift to an individual distribution system. The distribution of revenue to joint and collective purposes of rightsholders does not seem to be an adequate solution in the region.

Sustainability of the operations of the stand-alone organizations is high on the agenda of IFRRO as the international body grouping together RROs. While it may be important to encourage rightsholders in new countries to commence operations, sustainability of existing organizations needs to be ensured as the first priority. This also demands adequate technical infrastructure and WIPO's collaboration with IFRRO is hoped to result in workable systems to manage rights in the text and image sector.

## IN CONCLUSION

It is my hope that my experiences in working with Sub-Saharan rightsholders and their collective management organizations has shed some light into developments of a region which is seldom on the radar in copyright discussions. So much is happening and there is a will to make a difference for the creative sector. African are definitely rich in creativity and their creative output has greatly increased in popularity also in our part of the world, be it music, works of art or other creative products.

It has been a pleasure to work together with colleagues from the region and to see how they make a difference in their daily work.



**Ms. Tarja Koskinen-Olsson**

My core competences include exercise and management of copyright and related rights in different creative sectors: music, audiovisual, literature and visual arts. Good regulatory framework, corporate governance and effective management of rights are of special interest to me. As International Adviser and Chairperson of the Board at OK Consulting, I serve creators and other rights holders worldwide.

## Stoccolma per Marianne

# Which innovation is worthy of patent protection in the era of incremental innovation?

By Gustavo Ghidini, Emeritus, University of Milan; Senior professor of IP and Competition Law, LUISS University, Rome.

### 1 THE INFLUX OF INCREMENTAL INNOVATION

Long, long “gone are the days” of the XIX parameter of a ‘flash of genius’ to define the qualitative level of an innovation deserving of a patent.

That parameter went out, as known, due to the evolution of modern R&D dynamics, chiefly consisting (unlike the groundbreaking ones of the first industrial revolution) in painstaking processes made up of progressive even small but quite costly steps carried on by trial and error (J. Reichman) by complex teams of specialist researchers, working with sophisticated computing and scientific equipment.

No wonder, then, that a clear tendency emerged and became established in favor of lenient criteria of patentability, so as to include the fruits of *incremental innovation*.

This took place progressively.

The classic regime dictated two distinct substantial requirements for a valid patent, which expressed the innovative nature of the invention: *novelty* in the historical sense (‘extrinsic’ novelty), namely objective differentiation from known technical solutions; and *originality* (‘intrinsic’ novelty), namely the objective inventive step ahead of the body of existing knowledge, i.e. the prior art.<sup>1</sup>

The interpretative development which led to the 1974 European Patent Convention and the ensuing national legislations, recognized that a given solution is original (‘involves an inventive step’) only ‘if, having regard to the state of the art, it is not obvious to a person skilled in the art’ (article 56 of the EPC). The *Note* to article 27(1) of the TRIPs Agreement, which is an integral part of the text thereof, follows the same line: ‘inventive step’ is defined as being synonymous with ‘non-obvious’.

In other words, achieving an *objective* progress vis-à-vis prior art (while evoking a broad societal rationale of patent protection, and being the object of a disclosure duty by the applicant, ex Rule 42c, Regulation to EPC) does not as such constitute, according to the dominant interpretation, a requirement for patentability. It neither defines or complements the statutory requirement of ‘non-obviousness’. The assessment of an ‘important technical advance of considerable economic significance’ as positive legal

requirement is relevant *only* in the context of the special regime granting a compulsory (cross-) license under the provision of art. 31(l) TRIPs.

### 2 CONTEMPORARY ‘INDULGENCE’, AND ITS COROLLARIES

Thus, at the end of the day, exclusive protection is also granted to innovations of modest ‘originality’, provided that the innovation cannot be easily deduced from the prior art by a person skilled in the art.<sup>2</sup> An approach that could ultimately lead to the requisite of non-obviousness being substantially absorbed by that of objective novelty (and not vice versa, as would be more logical).<sup>3</sup>

As a rather obvious consequence of the reduced selectivity of access to patents, it becomes relatively easy for competitors to ‘elude’ the exclusionary rights of the patent holder. In fact, the modest degree of originality deemed sufficient to obtain a patent would more easily allow distinct solutions to be classed as ‘non-equivalents’ (not mere variations implementing the same idea solution), hence more easily obtain an independent (‘free’) status – including their own independent patentability. Indeed, ‘For the purpose of determining the extent of protection conferred by a [European] patent, due account shall be taken of any element which is equivalent to an element specified in the claims’ (Protocol on the Interpretation of Article 69 EPC of 5 October 1973, n.2).

In sum, the assessment of ‘inventive character’ and that of actual infringement are closely connected: if the invention is ‘non-obvious’, it is not, by definition, ‘equivalent’ to a previous one, thus does not infringe it. Now, as hinted, a ‘loose’, low-key assessment of inventiveness will logically correspond to a generous evaluation of ‘non-equivalence’ of the subsequent innovation. The author of the latter will more freely enter the market with her own solution (provided that this does not merely reproduce the prior patent). A result which would obviously be hampered if the prior patent were given broader protection based on a more ‘expansive’ assessment of ‘equivalence’.<sup>4</sup>

Is this, as one might at first sight infer, a positive result in terms of enhancement of dynamic competition (competition by innovation)? Let’s not be hasty. Some further analysis is called for in the light of a rethink in growing

areas of the legal (and business) world as to the level of inventiveness that should be required for granting a patent.

### 3 RISKS VIS-À-VIS THE FOSTERING OF DYNAMIC COMPETITION.

From about twenty years, in both Europe and the United States, a rising chorus of concern has critically commented the evoked trend to facilitate access to patents, favoring ‘the eagerness of even wise and able men to establish their priority in an unimportant discover’<sup>5</sup>.

Please don’t get me wrong here. The need to adapt the patent system (that is, protection of R&D against free riding) to the predominantly incremental nature of contemporary innovation is not being called into doubt. Rather, it is a question of degree. Incremental, as the very word itself (and economists) suggests, means to work on the results obtained by those who went before. It does not and must not mean ‘insignificant’.<sup>6</sup> Now, a legitimate doubt has grown that the evoked trend has gone too far in concrete terms so as to pose grave risks for a lively dynamic competition.

Here, the first and most immediate risk is that of scattering the path of subsequent innovators with others’

undeserving, negligible (‘poor quality’) patents, acting as arbitrary legal barriers, difficult and costly<sup>7</sup> to remove: with the ultimate effect of slowing down and discouraging technological progress. This risk becomes higher when a *patent thicket* is strategically used in order to hinder current or emerging minor competitors<sup>8</sup> – either by delaying their entrance into the market or imposing costly ‘settlements’ under the threat of a judicial offensive.<sup>9</sup> (That risk exponentially increases when patent thickets are held by dominant undertakings: which is more and more typically the case in ‘innovation markets’).

A second risk, linked to the first one, is more subtle but no less serious. I am referring to the possibility that thanks to a very slight change, at times a question of semantics consisting of a mere ‘clever turn of the phrase’<sup>10</sup>, the holder of a patent successfully resorts to the ploy of obtaining patents for subsequent *improvements* (that is, objectively derivative but held by the same person) in order to surreptitiously extend the length of the original exclusive rights beyond the statutory period of efficacy. This risk is indeed a real one, as confirmed by the widespread practices of so-called ‘evergreening’. For example, the filing patents that protect mere equivalents of the *main* patent nearing expiry, is a quite frequent *manoeuvre*,

<sup>1</sup> The validity of a patent presupposes from a substantive viewpoint that the invention entails a solution to a technical problem not yet resolved and is capable of industrial application such as to advance prior art and existing knowledge (*extrinsic novelty*) and is also an expression of a creative effort on the part of the inventor that is not just the mere execution of already known ideas falling within the normal application of known principles (*intrinsic novelty*).

<sup>2</sup> Although it can well be, in the specific case, a factual indicator of non-obviousness. On the subject see the in-depth essay by Hanns Ullrich, ‘Standards of Patentability for European Inventions: Should an Inventive Step Advance the Art?’, *IIC Studies in Industrial Property and Copyright*, 1, 1977. May I add (in possible disagreement, here, with Ullrich, *ibid.*, at 99 and fn 6) that ‘useless’/‘frivolous’ inventions can well be ruled as unpatentable on the basis of a serious application of the requirement of ‘industrial applicability’. See also R. Eisemberg, ‘Obvious to Whom? Evaluating Inventions from the Perspective of the PHOSITA’, *Berkeley Tech L. J.*, 2004, 885, in a comparative perspective, as offered by J. Bochovic, ‘The Inventive Step: Its Evolution in Canada, the United Kingdom and the United States’, *IIC Studies in Industrial Copyright and Copyright Law*, vol. 5, 1982. It is also worth considering the Italian Supreme

Court’s decision no. 13863 of 11 December 1999 (*Giur. Dir. Ind.*, 1999, p. 115), cited by Italian Supreme Court judgment no. 17993 of 9 September 2005 (*Foro It.*, 2006, I, 11), according to which patentability does not require any progress against a preceding invention aimed at solving the same problem: what is relevant is that it (the second invention) pursues said function with a different (and novel) technical solution.

<sup>3</sup> The judgment that a discovery is not obvious from the state of the art logically absorbs the preliminary one that it is not obvious across the board from that state. So much so that the contrary is impossible. Formally concentrating on the sole requisite of non-obviousness would serve not so much probably to simplify the procedure (the state of the art would still need to be preliminarily checked) but more to place greater emphasis on inventiveness and so in general raise the bar of non-obviousness beyond ordinary invention.

<sup>4</sup> The risk of extending the patent monopoly beyond what has been effectively invented by broadening the concept of ‘equivalent’ (especially in order to protect ‘pioneer inventions’, in which the breadth of the concept of equivalence translates into a ‘hunting licence’ over the derivative innovation in favour of the pioneering inventor, following the line in *Graver Tank and Mfg. Co. v. Linde Air Prods. Co.*, 339 US

605, 1950), is emphasized by E. Steinhauser, ‘Using the Doctrine of Equivalents to Provide Broad Protection for Pioneer Patents: Limited Protection for Improvement Patents’, *Pace L. Rev.*, 1992, 491.

<sup>5</sup> J. Ruskin, *Sesame and Lilies: The Ethics of the Dust*, Preface to the Second Edition, reprinted, Oxford University Press, 1951, 15.

<sup>6</sup> S. Scotchmer, ‘Standing on the Shoulders of Giants: Cumulative Research and the Patent Law’, *J. Econ. Persp.*, 1991, p. 29.

<sup>7</sup> On this type of risk see A. B. Jaffe and J. Lerner, *Innovation and its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It*, Princeton University Press, 2006.

<sup>8</sup> The remedy might consist in imposing heavy sanctions (along the lines of treble damages in the US) in favour of victims of sham litigation and above all expressly provide – at least in case law – that bringing such litigation may in itself constitute an act of unfair competition and even an antitrust violation in case the plaintiff enjoys dominant position.

<sup>9</sup> *Ex multis*, see J. Bessen, M. Meurer, J. Ford, and J. Laurissa, *The Private and Social Costs of Patent Trolls* (19 September 2011), Boston University School of Law, Law and Economics Research Paper No. 11-45, available at SSRN: <http://ssrn.com/abstract=1930272> or <http://dx.doi.org/10.2139/ssrn.1930272>.

<sup>10</sup> C. Bowe, ‘Merck Finds Tonic in Clever Turn of Phrase’, *Financial Times*, 29 March 2007.

especially in the chemical and pharmaceutical industries, in order to hinder/slow down the market entry of producers of generics.<sup>11</sup>

To combat such risk a specifically narrow interpretation/application of the notion of *inventive merit*, and a correspondingly broad notion of *equivalence*, should be adopted. Even more so when, as in the example just made, the derivative innovation is accomplished by the same holder of the original patent: for her, who has conducted the original research, it is normally much easier to develop improvements.

This is indeed the lesson to be learnt from the well-known 2013 judgment of the Indian Supreme Court in the *Glivec* case,<sup>12</sup> where the Judges rejected an application to patent a derivative pharmaceutical invention for lack of significant progress in terms of therapeutic efficiency compared to the original drug, by then off-patent.

This sound lesson against 'evergreening' is worth to be treasured: but with an important caveat.

One should be cautious about entrusting to patent offices the assessment of the efficacy of drugs in attaining a certain therapeutic result. Here, please recall the general statement made above: that 'inventive character' (*and, a fortiori*, 'novelty') is no legal synonym of 'economic or technical progress'. Hence, one should fully agree with the EPO's approach, which, in relation to the claim of therapeutic effect, refers to an assessment in terms of 'plausibility'. Right: no more than that. The 'true', ultimate assessment of therapeutic efficacy must be left (or however referred) to Public Health Authorities. This is to say that, beyond 'plausibility', patent offices should con-

centrate on the non-obviousness (strictly interpreted) of the invention: for this—not for preempting/'substituting' Health Authorities-- they are effectively equipped. Give Caesar...

#### 4 SIGNS OF A RETHINK

However, as hinted there are objective signs of a rethink : on both sides of the Atlantic. As regards Europe, one must consider the amendments to the European Patent Convention (introduced by 'EPC 2000', entered into force on 13 December 2007), which, by reforming the procedure before the EPO, significantly extend the room for disputing applications and for appealing decisions.<sup>13</sup>

Equally interesting is the signal coming from across the Atlantic with the reform of US patent law made by the Leahy-Smith America Invents Act (AIA) 2011, which *inter alia* extends the deadline for pre-issuance submissions and introduced the possibility for any interested party to bring opposition proceedings to contest the validity of a patent after its granting.<sup>14</sup> The reform was encouraged by many academics<sup>15</sup> as well as the US Supreme Court that, in *KRS International Co. v. Teleflex Inc. et al.* (550 US 2007), warned the USPTO to raise the bar of non-obviousness above 'ordinary innovation',<sup>16</sup> arguing that otherwise there was a risk that innovation might be stifled.<sup>17</sup>

#### 5 THE CASE OF 'STRATEGIC PATENTING'

The preceding hints to practices of 'evergreening' of near-to-expire patents evoke the broader subject of the so called "strategic patenting". The term refers to a set of heteroge-

neous unilateral<sup>18</sup> conducts (often picturesquely named by managers and lawyers), essentially aimed at enriching the patent arsenal and its 'offensive' capacity—practices typically, albeit not exclusively, implemented by big companies. If said companies hold a dominant position, those conducts may amount to an antitrust tort (unprejudiced, of course, their possible relevance as straight violation of IP law rules). In systemic terms, this possibility amounts to a competition law's interference with the entitlement/acquisition itself – not just the 'exercise'—of IPRs.

This type/level of interference follows preceding stages of the saga of the intersection of antitrust with IP law. In the first one, soon after the enactment of the Treaty of Rome, antitrust principles were used by Commission and Court to check IPRs' holders power to stipulate agreements that, profiting from the statutory territorial reach of IPRs, ultimately partitioned the European market, thus contradicting the foundational objective of a Single Market. At a subsequent stage, that of the emergence of the essential facilities (EF) doctrine, antitrust eroded the IPRs holders' power –statutory power!—to exclude third not authorized parties from access to over-the-top, not workably substitutable (in this sense 'essential') technologies. This, in order to avoid that the patent might turn out an instrument for monopolizing a sector of industry, instead of a specific solution in competition with effective substitutes. Accordingly, the IPR holder who also detained a dominant position, became subject to a duty to license in favor of 'willing licensees'---the straight absolute exclusionary remaining intact vs. sheer, die hard free riders. The last (so far) stage is the one we are focusing on here : that of antitrust checking the entitlement itself of IPRs (*Astrazeneca*, e.g.) and/or its misuse thru illicit practices of strategic patenting.

As to the ' pattern-book' of said practices, I have just above evoked the so-called *product hopping*, i.e. the introduction and patenting, in approximation of the expiry of a basic patent, of new versions thereof, at times with pseudo-improvements in an attempt to 'evergreen' the exclusive position. One might also think of the so-called *patent hoarding*, i.e. the amassing of patents outside the patentee's firm technological line ( patents, therefore, industrially 'useless' for the hoarder), but raked up either to prevent their purchase and exploitation by competitors, or for threatening minor competitors to stay out from the market 'or else' face a lengthy costly litigation—even a 'sham' one . Or of the creation of a dense network of patents - so-called *patent thickets* or *patent clusters* - concerning different formulations of the same invention, in order either to create uncertainty about the patent's scope or-- in the case of continuous filing of secondary applications--- about the duration of exclusive protection. And so on and so forth.

Taken together, these and other similar practices are the ultimate result of two main combined factors. One, economic, is the tendency towards concentration, particularly intense in the 'advanced' markets, including the pharmaceutical one (and that of digital media), constantly moving towards oligopolistic structures, and where com-



petition thru IPRs is particularly acute. The other is scientific and technological, and consists in the slowdown, more intense in certain sectors, of 'cutting-edge' innovation. It has been decades, for example, since effective antibiotics against new resistant strains of bacteria were developed.

The joint effect of these two factors is the pressure put on firms and groups, especially the big ones, to obtain as much IP protection and to 'squeeze' the IPRs attained as much and as long possible.

#### 6 FOLLOWS: SEPARATING THE WHEAT FROM THE CHAFF.

From a legal point of view these practices frequently make use of faculties per se granted by IP legal regime. Hence the borderline between lawful activities and conduct amounting to an 'abuse' is often thin (save for striking cases, such as the provision of misleading information to the patent Office, or the promotion, for 'black-mailing' purposes, of sham litigations). That borderline must therefore be sought with a cautious, Aristotelian attention to the specific circumstances of the single case – also because the abusive conduct is at time quite 'simple'

<sup>11</sup> The practice of extending the term of exclusive protection through improper filing of Supplementary Protection Certificates (SPCs) was the subject matter of the Italian case *Pfizer*, where the Competition Authority and the Council of State ruled that it constituted an abuse of dominant position to the detriment of generic drug manufacturers. See below, Chapter 5, section I.

<sup>12</sup> On 1 April 2013 the Indian Supreme Court rejected the appeal by the pharmaceutical company Novartis against a refusal to grant it an Indian patent regarding the beta crystal-line form of its anti-cancer drug containing imatinib, whose commercial name was *Glivec*, applying domestic legislation, specifically article 3(d) of the Indian Patent Act amended in 2005 precisely with the intent of combating evergreening. The Indian Supreme Court judgment contrasts with that made by other patent offices that had addressed the issue like the EPO and the USPTO. On the matter, see R. Abbott, *Of Evergreening and Efficacy: The Glivec Patent Case* (29 April 2013), available at SSRN: <http://ssrn.com/abstract=2258904>; S. Basheer and T. Prashant Reddy, "Ducking"

TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)", *National Law School of India Review*, 20, 2008, 131.

<sup>13</sup> Among the most significant changes is the amendment [arts 105(a), 105(b) and 105(c)] envisaging a new centralized procedure whereby at the request of the proprietor, the European patent may be revoked or be limited by an amendment of the claims with effect in all Member States. Also worthy of note is the first paragraph of article 105, whereby any third party who is a party to infringement proceedings may intervene in opposition proceedings at any time.

<sup>14</sup> See in particular 35 USC § 311 concerning the requests for *inter partes* re-examination and § 321 governing post-grant review.

<sup>15</sup> Among the first to stress the need for legislative change was R. Merges, 'As Many as Six Impossible Patents before Breakfast: Property Rights for Business Concepts and Patent System Reform', *High Tech. L. J.*, 14, 1999, 577. The reform was also encouraged by a Federal Trade Commission study of 2003, *Report on How to Promote Innovation Through Balancing Competition with Patent Law and Policy*, available at: <http://www.ftc.gov/reports/promote-innovation-proper-balance-competition-patent-law-policy>.

<sup>16</sup> "... the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle rather than promote, the progress of useful arts'. And again, "... granting patent protection to advances that would occur in the ordinary course without real innovation retards progress ...": *KSR Int'l Co. v. Teleflex Inc. et al.*, 550 US 2007.

<sup>17</sup> There is nothing to prevent the 'inventive character' being expressed by a specific component of the overall new invention. This in particular with regard to nanotechnological inventions, where, as clearly pointed out by P. Errico, 'La tutela brevettuale delle nanotecnologie', *Riv. dir. ind.*, 2007, I, 61, the invention often encompasses a mix of different technical and scientific disciplines such as chemistry, physics, IT, etc. Inventions in which, it must be added, that character does not necessarily derive from the combination per se of those elements.

<sup>18</sup> Thus, distinct from pay-for-delay agreements, a bi- or multilateral anti-competitive tort enforceable under art 81 Treaty.

(as in *Astrazeneca*), at times is an astute complex manoeuvre to be carefully reconstructed, as in the Italian *Pfizer* case.

(May I emphasize that the specific circumstances I'm referring to should be just *objective* ones. The intention to destroy competitors is permanently, I'd say physiologically, associated with the struggle for the market, so the interpret should not waste her/his time about 'intentions').

Thus, for example, with respect to cases of 'hoarding' competition authorities and Courts should give green light to conducts whereby the patents are actually raked to strengthen the core business of the patent holder (which certainly cannot be prohibited: except in the case of mergers, in the present stage of positive antitrust law firms cannot be prevented from 'overgrowing'). On the other hand, red light should be given when the hoarding concerns patents that a company of superior financial means does not actually employ nor is preparing to employ in its own business, but just uses them (e.g. by engaging, thanks to its 'deep pockets', in costly sham litigations) to cut the grass under the feet of rivals of minor financial means, who are engaged in the search for substitute technologies.

Similarly, I would be wary of outright condemning product hopping in case a patent is sought on a new mode of administering a drug, before checking whether the proposed new method is a Dulcamara hotchpotch<sup>19</sup> rather than, as is the case with certain chemotherapies, an effective albeit incremental means of 'slow release' that enhances the therapeutic efficacy or reduces the discomforts associated with assuming a certain type of drug. And so on.

## 7 AN OVERALL RATIONALE: FOSTER 'TRUE' INNOVATION

The specific rationale for enforcing abusive forms of strategic patenting is quite evident. It is a policy that aims to 'free competition' from unjustified obstacles through a selective approach to access to patents (and techno-copyright<sup>20</sup>) protection. So it shares the same objective of the evoked trends to discourage 'poor quality' patents, in line with the philosophy of, i.a., the quoted *KRS Int' v. Teleflex* decision.

May I emphasize, in concluding my reflection, that the risk of an inflation of unjustified obstacles to competition is even more evident, and serious, in relation to 'technology copyright', i.e. the copyright protection of software. This, because of the low level of 'creativity' traditionally required to access copyright protection. Now, such low level was, and is justified, in the name of freedom of expression, with respect to 'traditional' copyrightable works: artistic and scientific ones, i.e. works of merely intellectual, non-utilitarian, fruition— indefinitely variable in the expressive profile, hence posing no problem of 'monopolization'.

But software - despite its fictitious assimilation (first in the US, then in Europe) to 'literary works' - is just and totally technology: it is indeed 'the' technology of our age. So, in order to receive exclusive protection, its 'creativity' should be assessed with the same rigor that the US SC, in *KRS*, demanded for patents.

A point for future reform.  
G.G.

<sup>19</sup> 'Doctor' Dulcamara [ 'Dolce e amaro', sweet and sour] is a comic character of Gaetano Donizetti's opera 'L'elisir d'amore'. He is a Venetian charlatan that administers fake medicaments.

<sup>20</sup> I refer to the copyright protection of computer programs ---- 'the' technological instrument of contemporary knowledge economy—introduced upon the initiative of a *National Commission on New Technological Uses of Copyrighted Works (CONTU)*, instituted under the first Clinton Administration, composed by representatives of the major IT industries, and orchestrated by a

*célèbre* Washington lobbyist, Bruce Lehman. The US legislator promptly followed suit with the 1980 Software Copyright Act; so did, ten years later, the European [Directive 91/250 EC, now 2009/24 EC. That ascription was nevertheless not accepted by/ within the Berne Convention, due to the opposition of many Developing Countries, worried of an incoming 'ITC neocolonialism']. That historical expansion beyond the classical boundaries of the area of 'literary [including scientific] and artistic works' - also supported by the fictitious assimilation of computer programs to 'literary works' [see

e.g. *Apple Computer Inc. v. Franklin Computer Corp.*, 714 F.2d 1240 [3rd Circ. 1983]-- granted a true bonanza esp. for big first movers of the software industry, who could enjoy a type of protection that—compared with that of patents—features substantially no cost and no tests of access, a 'huge' term of duration, no submission to compulsory licenses, no green light for follow-on competitors even for the mere elaboration (not just the commerce, as for patents) of derivative improvements.



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# Sub-setting and indication stacking in orphan drugs: a recipe for the future of exclusive rights

By Sven J.R. Bostyn

## 1 INTRODUCTION

The present article is, apart from the result of my own work and intellectual effort, also written for a special occasion. Professor Marianne Levin has turned a healthy age, and I have been asked by the current esteemed colleagues at the Stockholm Law Faculty to write a contribution for this special occasion. Scheduling this piece of work into my calendar was difficult, due to a list of other commitments, but I could not possibly refuse the honour, so I accepted. The reader might wonder how Professor Marianne Levin and I could possibly be linked. Well, many years ago, when I was still a young (and promising) student, I undertook postgraduate master studies in Stockholm. I decided at that time, which was in 1994-1995, to write my Master dissertation about the patentability of biotechnological inventions, and Professor Marianne Levin was my supervisor. You should know that around that time, the Biotech Directive<sup>1</sup> was still in negotiation at the European Commission and European Parliament, and even though there was already some, mostly descriptive, literature on the subject, it was a subject which most lawyers avoided carefully, as it was perceived (and it indeed materialised) to be a very difficult subject, which required some insight into principles of biotechnology, chemistry and biology, apart from the ever so challenging and complex patent law concepts. Marianne was the best supervisor one could have imagined. She provided me with all possible assistance. I remember that one of the administrative staff members at the law Faculty was quite upset, as I could use the copy machine on the floor of the small but well stocked library of what was then called "Institutet för Immaterialrätt och Marknadsrätt". Moreover, bad luck struck (the story of my life unfortunately) and my laptop (laptops were still a rarity those days) broke down. I was very upset about it, as it happened during the last months of my stay in Stockholm, and I had not yet developed the habit of making regular backups. I told Marianne about my misfortune, and she promptly offered her office and computer to me to continue the hard work on my Master dissertation. The only instruction was to answer the phone when it rang (in Swedish), inform the caller that she would be back the next day (also in Swedish), and inform Marianne who called. And so I did. She was also instrumental in providing me with additional funding to finalise my Master dissertation in Stockholm. After having seen some of the work I had delivered, she thought that I could handle speaking on a

conference organised by the Institute with speakers and an audience spanning the most distinguished people in IP law in Sweden (ranging from senior people at the Swedish Intellectual Property Office (PVR) over senior judges in patent law to partners and associates from some of the most prestigious law firms, and not to forget, some of the best IP academics in the country). To my own surprise, it went rather well (the only issue was that I did not have a suit, and being poor, I could not buy one for the occasion, so I had to do with a shirt and tie which I had hastily bought before the event). Having been offered that much support, I felt morally obliged to submit the best Master dissertation I could. I am sure I have even surprised Marianne when she received the final manuscript, which was no less than 380 pages (suffice to say that I exceeded the regular word limit), and I was happy to receive the highest grade for my effort. I have always kept fond memories of my time in Stockholm (even though I was poor as a student in what was then a very expensive country during pre-EURO currency and pre-EU times), and in particular also of Marianne, not only for her kindness, but also for her wit and intellect. She was (and I assume she still is) a very sharp thinker, and even though I would not want to venture into labelling character features on Swedish people, she gave me the impression of being (slightly) more direct and a "straight shooter" than most Swedes. It is safe to say that she gave me the confidence, but also the realisation that I maybe had a talent I was not aware of, i.e., that I was not the worst researcher one could find, and that realisation, together with an initial interest in doing academic research, has convinced me to continue focusing (among other things) on academic research. Whether it was a wise decision for me to become a (part-time) academic is another matter, but I will be eternally grateful to Marianne for giving me the possibility and confidence to do so.

When asked to contribute with an article, I was for a very long time in doubt what would be fitting for the occasion. I decided to go for something which is not fully mainstream and trodden path, in line also with my Master dissertation at the time in Stockholm, which covered a then very much under-researched area of the law. Having taken that decision, the choice became much easier. I decided to write about issues which are not very well researched in Europe, and which are in fact also not very well understood. So it is orphan drug exclusivities I have decided to write about here.

In this article, I want to focus on two, often intercon-

nected, features of the orphan drug exclusivity regime that require specific attention, and in my opinion also a remedy. Those features are the so-called sub-setting (also more endearingly referred to as salami slicing) and indication stacking. Even though I will explain those features more in detail in this article, I define them already briefly here so as to facilitate the further reading. Sub-setting or "salami slicing" refers to the practice of splitting certain common diseases into many 'artificial' subsets. Each of these subsets could then be considered a rare disease (such as certain forms of cancer). "Indication stacking" is the phenomenon where orphan products are authorised for two or more orphan indications on the market. These indications refer to distinct but sometimes also overlapping orphan conditions, and each entitles the product in question to a period of market exclusivity, which may run in parallel, with their own start and end dates.

I will demonstrate that the current regime relating to market exclusivities for orphan drugs is in need of change for future purposes. Even though there might not be a high number of cases pertaining to the practices which I will critically analyse in what follows in this article, it is my view that we should not wait to amend the regime until we are effectively confronted with a high number of such cases. We currently have around 17% of authorised orphan drugs which are the subject of indication stacking. That might not seem much, but it is better to regulate for the future than remedy for the past. To that effect, I make a number of proposals for further discussion. Some of these proposals are also options presented by the European Commission in its current evaluation of the orphan drug regime, whilst others are based on my own insights.

## 2 ORPHAN DESIGNATION

### 2.1 Introduction

For so-called orphan diseases, the definition of which will follow later in this section, one of the key problems has been, and that already for many years, how to incentivise R&D into and marketing of orphan drugs. Indeed, one of the difficult issues has been how to provide incentives to

industry to develop drugs for rare diseases. Main reason why this is a problem is that those diseases affect only small patient populations, which makes it in general not very attractive for drug developers to make the investment in developing drugs as the market will by definition be quite small. Pharmaceutical companies to a large extent use a business model where they can sell large volumes of product with hopefully, at least for some period of time, some exclusivity rights, be it patents or regulatory exclusivities,<sup>2</sup> which allows them to charge higher prices than such would be the case if there were full competition with other manufacturers. The large volumes combined with the higher than competition prices allow them not only to recoup the investment, but also take a good profit, which can be used for further R&D, and partly offsets also the losses made by failed projects.<sup>3</sup> This is also confirmed in a recent European Commission Staff Working Document: "At the end of the 1990s, the pharmaceutical market was dominated by big companies, which were often interested in developing 'blockbusters' that could be sold in large volumes to tackle common diseases. By contrast, the costs of research and development meant that industry was often disinclined to invest in developing remedies for diseases with small numbers of patients."<sup>4</sup>

It was perceived that traditional already existing incentives (8+2 years data and market exclusivity<sup>5</sup> and patent,



<sup>1</sup> Directive 98/44/EC on the legal protection of biotechnological inventions, OJ L 213, 30/07/1998.

<sup>2</sup> With "regulatory exclusivities" is meant data and market protection, also called data and market exclusivity.

<sup>3</sup> It is very difficult, if indeed possible at all, to obtain precise insight into the cost and profit structure of pharmaceutical companies, hence the profit margins and the rate of failed projects (the details of which remain largely secret and unpublished) is very difficult to discover.

<sup>4</sup> COMMISSION STAFF WORKING DOCUMENT – EVALUATION. Joint evaluation of Regulation [EC] No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on

medicinal products for paediatric use and Regulation [EC] No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, {SEC(2020) 291 final} - {SWD(2020) 164 final}, Brussels, 11.8.2020, (hereinafter COMMISSION STAFF WORKING DOCUMENT, 2020), Part 1/6, p. 10 ([https://ec.europa.eu/health/system/files/2020-08/orphan-regulation\\_eval\\_swd\\_2020-163\\_part-1\\_0.pdf](https://ec.europa.eu/health/system/files/2020-08/orphan-regulation_eval_swd_2020-163_part-1_0.pdf)).

<sup>5</sup> European law works with the so-called 8+2+1 system for regulatory exclusivities. There is 8 years of data exclusivity, an additional extra two years of market exclusivity (which starts at the same time as the data exclusivity, but lasts two years longer, bringing its total life span to 10 years). One additional year of

market exclusivity may be granted for new therapeutic indications showing significant clinical benefit in comparison with existing therapies (art. 10(1), para. 4); one year of data protection for new indications of well-established substances (art. 10(5)); and one year of protection for data supporting a change of classification (e.g., from prescription drug to over-the-counter) (art 74a). These additional terms of exclusivity are not cumulative, so the total duration of protection cannot exceed eleven years. All statutory references herein are to 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 (as amended later), OJ L 311, 28.11.2001, p. 67-128.

including SPC, protection<sup>6,7</sup>) for “regular” drugs were not sufficient to entice companies to invest substantially in developing drugs to fight rare diseases, reason why policy makers looked at other incentive mechanisms to ensure that more treatments were being developed for those rare diseases.

Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products,<sup>8</sup> as amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009,<sup>9</sup> lays down procedures for the designation of medicinal products as orphan medicinal products and for the marketing authorisation of such products. The rationale for the incentives required for orphan diseases is expressed in Recital 8 of Regulation 141/2000, which reads:

“[E]xperience in the United States of America and Japan shows that the strongest incentive for industry to invest in the development and marketing of orphan medicinal products is where there is a prospect of obtaining market exclusivity for a certain number of years during which part of the investment might be recovered; data protection under Article 4(8)(a)(iii) of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products [OJ, English Special Edition, 1965, p. 20] is not a sufficient incentive for that purpose; Member States acting independently cannot introduce such a measure without a Community dimension as such a provision would be contradictory to Directive 65/65/EEC; if such measures were adopted in an uncoordinated manner by the Member States, this would create obstacles to intra-Community trade, leading to distortions of competition and running counter to the single market; market exclusivity should however be limited to the therapeutic indication for which orphan medicinal product designation has been obtained, without prejudice to existing intellectual property rights; in the interest of patients, the market exclusivity granted

to an orphan medicinal product should not prevent the marketing of a similar medicinal product which could be of significant benefit to those affected by the condition.”

The literature recognises that many orphan diseases would not have received the appropriate treatment if there would not have been incentives provided to the pharmaceutical sector to develop treatments for those rare conditions.<sup>10</sup>

As it was said in the aforementioned European Commission Staff Working Document relating to the Orphan Drug Regulation,

“the specific objectives of the Orphan Regulation are to:

- Ensure research and development and the placing on the market of designated orphan medicinal products (availability) (specific objectives 1 and 2);
- Ensure that patients suffering from rare conditions have the same quality of treatment as any other patient (accessibility) (specific objective 3).”<sup>11</sup>

A medicinal product can only be designated as an orphan medicinal product if a number of conditions are being fulfilled, which can be found in Art. 3(1) Regulation 141/2000:

“A medicinal product shall be designated as an orphan medicinal product if its sponsor can establish:

- (a) that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the [European Union] when the application is made, or
- that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the [European Union] and that without incentives it is unlikely that the marketing of the medicinal product in the [European Union] would generate sufficient return to justify the necessary investment,

and

- (b) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the [European Union] or, if such method exists, that the medicinal product will be of significant benefit<sup>12</sup> to those affected by that condition.”

There are hence two categories of conditions that could trigger the orphan designation.

The first category is based on what is called “prevalence”, in the case of the European orphan drug designation system it means that it concerns a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the [European Union] when the application is made. The second category is based on return on investment, i.e., without incentives it is unlikely that the marketing of the medicinal product in the [European Union] would generate sufficient return to justify the necessary investment.

It appears that the vast majority of applications for orphan drug designation status are based on the first category, i.e., prevalence.<sup>13</sup> In fact, by the end of 2017, only one application had been received under the ‘insufficient return on investment criterion’, and that was subsequently withdrawn.<sup>14</sup>

With a view to ensure that the pharmaceutical industry invests sufficient funds in the treatment of rare diseases, for which a sufficient financial return is not guaranteed, the Orphan Drug Regulation<sup>15</sup> has introduced an incentive in the form of a stand-alone period of 10 years of market protection (or market exclusivity, both being the same thing).<sup>16</sup> An additional 2 years of market exclusivity can be obtained in case of a paediatric use.<sup>17</sup> Other incentives which the Orphan Drug Regulation provides, but which are beyond the scope of this article are access to the centralised procedure at EMA,<sup>18</sup> possible fee reductions,<sup>19</sup> and incentives to invest in R&D for orphan diseases, in particular to SME’s.<sup>20</sup> As said, we will limit ourselves to the ten years market exclusivity.



## 2.2 How the system works

In Europe, orphan medicinal products (OMPs) are designated by the European Commission on receipt of a positive opinion from the selected regulatory body – the Committee for Orphan Medicinal Products (COMP) – via a process commonly known as orphan drug designation (ODD). ODD can be granted at any stage in the medicine’s development. Opinions for designations are based on the following criteria:<sup>21</sup>

- The rarity of the condition (affecting no more than five in 10,000 people in the EU) or evidence of insufficient return in investment
- Seriousness of the disease/condition
- The existence of alternative methods of prevention, diagnosis or treatment (the EU stipulates that this should be a novel form of therapy for the condition; however, if there is an existing form of therapy, the orphan product must be of significant benefit to the patients and must have an advantage over existing therapies).<sup>22</sup>

<sup>6</sup> Under European patent law, there is 20 years of patent protection. There is additionally a maximum of 5 years of additional SPC protection, using the calculation formula laid down in Art. 13 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 (OJ L 152, 16.6.2009, p. 1–10). According to that formula, the exact SPC term, which is in effect expressed in days, is equal to the difference between the time period between the filing date of the patent and the date of grant of the marketing authorisation, minus 5 years. For example, if the patent has been filed on 1 February 2010 and the marketing authorisation for a medicinal product protected by the patent with the aforementioned filing date is granted on 1 October 2020,

the difference between the two is 10 years and 8 months. One must now subtract 5 years from that period, which is 5 years and 8 months. As the maximum term of protection for an SPC is 5 years, the SPC term for this example will be 5 years. The maximum term will be less than 5 years. There is also a one off 6 months paediatric extension upon approval of a Paediatric Investigation Plan (PIP) (Art. 36(1) of Regulation (EC) No 1901/2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004. See also Art. 13(3) Regulation 469/2009).

<sup>7</sup> Under current case law, SPC protection will be very difficult to obtain for second and further medical use claims if the product which is

invoked for the SPC has already been the subject of an earlier marketing authorisation as a medicinal product, even though there might never have been an earlier patent for that product, and even if the further medical use is for an entirely different disease than the earlier marketing authorisation. See ECJ case C-673/18 *Santen SAS v Directeur général de l’Institut national de la propriété industrielle*, judgment of the Court (Grand Chamber) of 9 July 2020, ECLI:EU:C:2020:531.

<sup>8</sup> OJ 2000 L 18, p. 1.

<sup>9</sup> OJ 2009 L 188, p. 14.

<sup>10</sup> V. GIANNUZZI, R. CONTE, A. LANDI, S.A. OTTOMANO, D. BONIFAZI, P. BAIARDI, F. BONIFAZI, A. CECI, ‘Orphan medicinal products in Europe and United States to cover needs of patients with rare diseases: an increased common effort is to be foreseen’

[2017] Orphanet Journal of Rare Diseases, 12:64.

<sup>11</sup> COMMISSION STAFF WORKING DOCUMENT, 2020, p.12.

<sup>12</sup> Is further defined in Art. 3(2) Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts ‘similar medicinal product’ and ‘clinical superiority’ as: “a clinically relevant advantage or a major contribution to patient care.”

<sup>13</sup> A. DENIS, L. MERGAERT, C. FOSTIER, I. CLEEMPOT, S. SIMOENS, ‘Issues Surrounding Orphan Disease and Orphan Drug Policies in Europe’, [2010] Appl Health Econ Health Policy; 8 (5): (343-350) 345.

<sup>14</sup> COMMISSION STAFF WORKING DOCUMENT,

2020, p.43.

<sup>15</sup> REGULATION (EC) No 141/2000 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 1999 on orphan medicinal products, OJ 22.01.2000, L 18/1.

<sup>16</sup> Art. 8 Regulation 141/2000.

<sup>17</sup> Which is not compatible, however, with filing for a paediatric extension of a SPC. The applicant has to choose between going for a two additional year market protection for an orphan drug for paediatric use, or go for a one-off 6 months paediatric extension of an existing SPC, provided a Paediatric Investigation Plan (PIP) has been approved. See, Art. 36(4) of Regulation (EC) No 1901/2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004.

See also Art. 13(3) Regulation 469/2009.

<sup>18</sup> Art. 7 Regulation 141/2000.

<sup>19</sup> Art. 7 Regulation 141/2000.

<sup>20</sup> Art. 9 Regulation 141/2000.

<sup>21</sup> See Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts ‘similar medicinal product’ and ‘clinical superiority’.

<sup>22</sup> See for this, R. OGBAH, ‘Orphan medicinal products – A European process overview’ [2015] 12/2 Regulatory Rapporteur, 5-11, at 5.



more so for paediatric orphan diseases, the incentive system has not led to any meaningful uptake in drug development.<sup>26</sup> That is a first concern. However interesting and relevant this is, it is not the central focus of the present article, and will remain further undiscussed.

### 2.3 The exclusivity periods

As said, as an incentive reward to bring to market drugs for rare diseases, the orphan drug Regulation provides a “prize” of 10 years of market protection. Talking about that market exclusivity, we need to make a couple of important observations.

First, it must be emphasised, that the provision is worded in a somewhat peculiar manner, suggesting the 10 years exclusivity in fact to be a kind of hybrid of data and market protection. Indeed, the text of the relevant provision states that “the [European Union] and the Member States **shall not, for a period of 10 years, accept another application for a marketing authorisation**, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product” (emphasis added).<sup>27</sup> Data exclusivity is there to prevent generics to file for a MA (in which the generic refers to the file of the reference product which has already been authorised). Market protection does not prevent generic versions of the reference product being filed, but it merely prevents generics from entering the market during the market protection period.

The wording of the orphan drug market protection suggests that an application cannot be accepted during the 10 years of market protection, which implies that generics can only file at the end of the 10 years market protection period, which gives a de facto longer period of market protection, as obtaining a MA for a generic version of an orphan drug after filing date can take around 1.5 years. This issue has mostly been overlooked in the literature, but it is worth noting, as it puts generic manufacturers in a competitive disadvantage compared to “regular” medicinal products (where they can file for a generic MA after the 8 years data exclusivity, so as to enter the market on day 1 after the end of the 10 years market exclusivity period).

Another important feature is that, unlike for “regular” medicinal products,<sup>28</sup> there are ways how multiple cumulative market protection periods can be obtained for similar orphan medicinal products.<sup>29</sup> One of the options is laid down in Art. 8(3) Regulation 141/2000:

“3. By way of derogation from paragraph 1, and without prejudice to intellectual property law or any other provision of [EU] law, a marketing authorisation may be granted, for the same therapeutic indication, to a similar medicinal product if: (a) the holder of the marketing authorisation for the original orphan medicinal product has given his consent to the second applicant, or (b) the holder of the marketing authorisation for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product, or (c) the second applicant can establish in the application that the second medicinal pro-

duct, although similar to the orphan medicinal product already authorised, is safer, more effective or otherwise clinically superior.”<sup>30</sup>

The above describes the situation that similar orphan medicinal products can benefit from multiple market exclusivity periods, provided that the conditions under Art. 8(3) Regulation 141/2000 are being met. One such option would be that the first MA holder grants consent to a second MA holder for a similar medicinal product for the same therapeutic indication. It is hence also possible to accumulate market exclusivity periods for the same therapeutic indications.

But another option to accumulate market exclusivity periods is under the scenario that the same active substance becomes the subject of multiple orphan drug designations, and to the extent that two or more of those orphan drug designations lead to a MA, the same active substance will lead to multiple MA’s (for different therapeutic indications), and for each of those MA’s, a separate

10 years exclusivity period is triggered. That also allows to accumulate market exclusivities. Take for instance active substance A for orphan drug indication X, for which an MA is obtained on 1 May 2005. If for that same substance A another orphan drug indication Y is found, and if that leads to another MA, for instance on 1 October 2010, that second MA will trigger its own 10 years exclusivity period. That means that active substance A for orphan drug indication X will benefit from market exclusivity until 1 May 2015, and that same active substance A for orphan drug indication Y will benefit from 10 years market exclusivity until 1 October 2020. It is not uncommon that in such a scenario, the orphan drugs indications for which the multiple MA’s have been granted overlap, which de facto extends to a potentially longer than 10 years period of some form of exclusivity in active substance A. In our example market exclusivity on the active substance in some form will extend from 2005 to 2020 (see also Figure 1 for a graphic representation).

The procedure relating to orphan medicinal products consists of two separate phases:<sup>23</sup>

1. designation – this can take place at any stage of development prior to the submission of a marketing authorisation application, provided that the sponsor can establish that the criteria in Article 3 of the Regulation are met. Designation has no effect on parallel developments by different sponsors. It is a tool to identify candidate products in a transparent way and to make them eligible for financial incentives. Designation will be confirmed by a separate Commission decision for each candidate product and the designated product will be entered in the Community Register for Orphan Medicinal Products (Article 5 of the Regulation);

and

2. marketing authorisation (MA).

The statistics demonstrate that the very large majority of orphan drug designations never makes it to an MA. Between 2000 and 2017, 1956 designations were granted and 142 orphan medicines were authorised (11 were subsequently withdrawn, thus leaving 131 on the market).<sup>24</sup> The most important regulatory exclusivity, i.e., the 10 years market exclusivity is only available for those orphan drug products that obtain an MA.

There have been critical observations as to whether the orphan drug system fulfils its promise. A rather large share is for anti-cancer treatments, followed by treatments for conditions of the alimentary tract and metabolic disorders.<sup>25</sup> As was established in the 2018 Report I co-authored, for quite a few of orphan diseases in general and even

<sup>23</sup> Case T-74/08, *Now Pharm AG v European Commission*, ECLI: EU:T:2010:376, paragraph 33.

<sup>24</sup> COMMISSION STAFF WORKING DOCUMENT, 2020, p.35.

<sup>25</sup> COMMISSION STAFF WORKING DOCUMENT, 2020, p.24.

<sup>26</sup> T. DE JONG, A. RADAUER, S.J.R. BOSTYN, J. POORT, ‘Effects of Supplementary Protection Mechanisms for Pharmaceutical Products’, May 2018, Technopolis Group, 169 pp (hereinafter Technopolis Report 2018), downloadable at <https://www.technopolis-group.com/report/effects-of-supplementary-protection-mechanisms-for-pharmaceutical-products/>, p. 98-99.

<sup>27</sup> Art. 8 of Regulation No 141/2000, which reads in full: “1. Where a marketing authorisation in respect of an orphan medicinal product is granted pursuant to [Council] Regulation (EEC) No 2309/93 [of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 241, p. 1)] or where all the Member States have granted marketing authorisations in accordance with the procedures for mutual recognition laid down in Articles 7 and 7a of Directive 65/65/EEC or Article 9(4) of Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products [OJ 1975 L 147, p. 13], and without prejudice to intellectual property law or any other provision of [EU] law, the [European Union] and the Member States shall not, for a

period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product.”

<sup>28</sup> For “regular” medicinal products, the so-called GMA, discussed further below, would prevent that.

<sup>29</sup> Art. 3(3)(b) Regulation (EC) No 847/2000 defines “similar medicinal product” as a “medicinal product containing a similar active substance of substances as contained in a currently authorised orphan medicinal product, and which is intended for the same therapeutic indication.” The concept of “similar active substance” is in turn defined in the same Art. 3 sub 3(c) as: “an identical active substance, or an active substance with the same principal molecular structural features [but not necessarily all of the same molecular structural features] and which acts via the same mechanism.” It includes in any event isomers, mixture of isomers, complexes, esters, salts and non-covalent derivatives of the original active substance, or an active substance that differs from the original active substance only with respect to minor changes in the molecular structure, such as a structural analogue.

<sup>30</sup> Is further defined in Art. 3(3)(d) Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts ‘similar medicinal product’ and ‘clinical superiority’: “‘clinically superior’ means that a medicinal product is

shown to provide a significant therapeutic or diagnostic advantage over and above that provided by an authorised orphan medicinal product in one or more of the following ways:

(1) greater efficacy than an authorised orphan medicinal product [as assessed by effect on a clinically meaningful endpoint in adequate and well controlled clinical trials]. Generally, this would represent the same kind of evidence needed to support a comparative efficacy claim for two different medicinal products. Direct comparative clinical trials are generally necessary, however comparisons based on other endpoints, including surrogate endpoints may be used. In any case, the methodological approach should be justified;

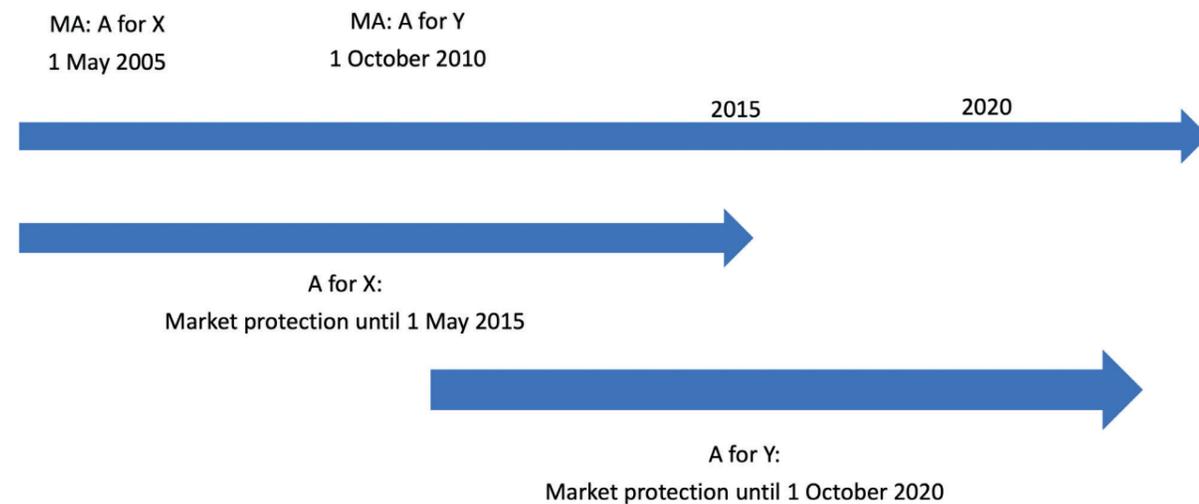
or

(2) greater safety in a substantial portion of the target population(s). In some cases direct comparative clinical trials will be necessary;

or

(3) in exceptional cases, where neither greater safety nor greater efficacy has been shown, a demonstration that the medicinal product otherwise makes a major contribution to diagnosis or to patient care.”

Figure 1:



The above is possible for orphan drugs because of the absence of the so-called Global Marketing Authorisation (GMA) concept for orphan drugs. That means that the same active substance can obtain multiple orphan drug designations, and for each of those that leads to an orphan drug MA, a separate 10 years market exclusivity is triggered.

The concept of “global marketing authorisation” is a crucial one for “regular” drugs as it is the trigger of the regulatory exclusive rights which are the subject of this article. **Once a medicinal product has been authorised, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions which could become authorised in the future will all fall within the same global marketing authorisation and cannot trigger a separate entitlement to regulatory exclusivity, such data and market exclusivity. All these variations and extensions will not be entitled to their own data and market exclusivity, at least in principle.**<sup>31</sup> Thus, the GMA contains the initial authorisation and all of the above-mentioned variations. In other words, as long as the product is held to be the “same” active substance, all changes to that active substance as laid out above cannot trigger a separate period of regulatory exclusivity, but all fall within the same GMA. That is of course important, as drug developers must take into account that any such changes will not benefit from additional regulatory exclusivity protection, apart from the rather limited cases set out above. There are a limited number of exceptions, where a 1 year extension can be obtained.<sup>32</sup>

This is different from patent law, for instance, where different salts, pharmaceutical forms or administration routes could be protected separately by patents, provided that they are found novel, inventive and sufficiently

disclosed. The regulatory system is not that generous in the context of regulatory exclusivity protection. That probably also explains why pharmaceutical companies have been focussing so heavily on obtaining patent protection, absent any other means of obtaining exclusivity in the regulatory framework.

A good illustration of the issues is case C-629/15,<sup>33</sup> where the issue was whether Novartis could invoke data exclusivity protection for a MA obtained for Aclasta, which had zoledronic acid as the active substance, for specific medical indications, whilst there was an earlier MA for Zometa, also having the active substance zoledronic acid but for different medical indications. The generic pharmaceutical companies referred to Aclasta as the reference product in this case, and Novartis claimed that, as the companies filed to register the active substance for medical indications falling under the Aclasta product, it was entitled to a separate period of data and market exclusivity for Aclasta, which, in case Aclasta would have generated a new period of data and market exclusivity, it would not have lapsed at the time of filing for MA's by the generic pharmaceutical companies.

By the decisions at issue, the Commission granted MAs for Z.a. Teva and for Z.a. Hospira.<sup>34</sup> Novartis appealed the decision to grant a MA for Z.a. Teva and for Z.a. Hospira, arguing that this was an infringement to Art. 10(1) Directive 2001/83. It claimed that it was entitled to data exclusivity for 10 years based on the MA for Aclasta. It was claimed in this case that a MA for specific medical indications relating to an active substance that had already been subject to a MA for different medical indications earlier did not fall under the same “GMA” generated for the first MA, and that the MA holder for the later medical indications was hence entitled to a new period of data and market exclusivity for the later MA for the medical indications.

The CJEU did not follow this reasoning and held that the MA for the further medical indications of the active substance could not generate a new “GMA” and hence entitlement to a fresh period of data and market exclusivity, but that those further indications all fell within the scope of the “GMA” already generated by the MA for the active substance earlier, even if this was for different medical indications.

The case arrived at the CJEU after an appeal by Novartis against the judgements of the General Court in this case.<sup>35</sup> The CJEU confirmed the reasoning of the General Court and held that all the different medical indications and strengths of zoledronic acid, which in the case of Novartis, had been the subject of two different MA's, belong to the same GMA and can consequently not lead to two separate periods of data and market exclusivity, but fall all within the same period of data and market exclusivity.

As said, it has been decided not to make the concept of GMA applicable to orphan drugs, so as to make the incentive more attractive. Indeed, the existence of a GMA concept for orphan drugs would largely prevent accumulation of market exclusivities, whilst its absence allows accumulation of the same, as we will see in more detail in what follows.

The fact that multiple market exclusivities can be granted for the same active substance, be it for different orphan drug indications, can pose problems for generic entry. If the product (for instance the “pill” formulation) on the market as an orphan drug product is still under market exclusivity, no generic entry can take place. In principle, for each of the orphan drug indications for which there is no longer orphan drug market exclusivity, generic entry is possible. However, if it is the same active substance in the same formulation, this might very well lead to infringement issues. Using the example I laid out earlier, if gene-

ric orphan drug A is on the market for indication X that is no longer under market exclusivity, but it can also be used in a cross-label fashion for indication Y which is still under market exclusivity,<sup>36</sup> this could lead to infringement problems, and might de facto delay generic entry. I will explain this more in detail in what follows, and it also brings us to the issues of sub-setting and indication stacking.

Cross-label use is the practice where a physician prescribes a generic version of an innovator drug that has been authorised for the protected use. In other words, the physician prescribes a generic drug, which in itself is not authorised for a specific orphan drug use under protected, but the it is a drug which is bioequivalent to an innovator drug which benefits still from market exclusivity for an orphan drug use. The situation is especially prevalent in situations of repurposing of drugs, i.e., the situation where an existing drug benefits from market exclusivity for a new orphan drug use. As the active substance is already on the market, and indeed generic entry is legally allowed for certain uses (and provided the formulation of the active substance remains substantially the same), it is quite common for physicians to prescribe that generic version for a use which still benefits from (orphan) drug exclusivity. It is common for both “regular” drugs and orphan drugs. The major difference is that, as “regular” drugs use the GMA concept, repurposing is largely unrewarded under regulatory exclusivities (apart from a once 1 year extension in specific cases). Cross-label prescription will consequently not have any fundamental consequences under the regulatory exclusivity regime for regular drugs (but it has for patent protection though).<sup>37</sup> For orphan drugs, the situation is quite different indeed. As orphan drugs do not use the GMA concept, the accumulation of exclusivities does present potential problems regarding infringement and regulatory exclusivities.

<sup>31</sup> Article 6(1) second subparagraph of Directive 2001/83/EC, of the European Parliament and of the Council of Nov. 6, 2001 on the Community Code Relating to Medicinal Products for Human Use (hereinafter Directive 2001/83/EC): “When a medicinal product has been granted an initial marketing authorisation in accordance with the first sub-paragraph, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation in accordance with the first sub-paragraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10(1).”

<sup>32</sup> One year extension of the 10 year period in Article 10(1) in the case of 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 (Art. 10(4) Directive 2001/83; Art. 14(11) of Regulation (EC) No 726/2004); One year period of data protection for new indications of well-established substances (Article 10(5) of Directive 2001/83/EC. For a definition of well-established substance and use, see Part II of the Annex to Directive 20001/83/EC as amended by Directive 2003/63/EC); One year period of protection for data supporting a change of classification (Article 74a of Directive 2001/83/EC, introduced by Directive 2004/27/EC)..

<sup>33</sup> C-629/15, *Novartis Europharm Ltd v. European Commission*, ECLI:EU:C:2017:498.

<sup>34</sup> *Ibidem*, para 15-20.

<sup>35</sup> *Novartis Europharm v. Commission* (T-472/12, EU:T:2015:637), and *Novartis Europharm v. Commission* (T-67/13, not published, EU:T:2015:636).

<sup>36</sup> This is by no means a theoretical scenario. Cross-label use is frequently done, also with a view to save costs for public health care systems. Moreover, there is also evidence that off-label use in the paediatric environment is even more rampant: “Depending on the therapeutic area concerned, between 50% and 90% (for example, cancer treatments and HIV treatments) of authorised medicines in the EU were used off-label in children, i.e., without their effects on children having been studied.” See, COMMISSION STAFF WORKING DOCUMENT, 2020, p.20.

<sup>37</sup> For more details on cross-label prescription and patent infringement problems, see, S.J.R. BOSTYN, ‘Personalised medicine, medical indication patents and patent infringement: emergency treatment required’, [2016] Intellectual Property Quarterly, 151-201 [hereinafter BOSTYN, IPQ, 2016a].

### 3 SUB-SETTING (SALAMI SLICING), INDICATION STACKING AND DELAY TO GENERIC ENTRY

It is in the context of generic entry delay that I want to discuss two specific features which are made possible under the orphan drug system in Europe, i.e., sub-setting and indication stacking.

Indeed, it has been pointed out in the literature<sup>38</sup> that, although the system of orphan designation is designed to grant orphan status to an appropriate drug, the current system can be (mis)used to artificially create orphan drugs or orphan diseases.<sup>39</sup> This can happen when drugs are developed for a specific type of patient/disease (a practice called ‘targeting’), or when one disease is split into various subcategories, each of which exhibits its own characteristics (a practice called “sub-setting”).<sup>40</sup> Sub-setting can lead to so-called “salami-slicing”, where artificial subsets of a non-orphan disease are created, with a view to qualify as several orphan diseases.<sup>41</sup> Indeed, the phenomenon of salami-slicing refers to splitting certain common diseases into many ‘artificial’ subsets. Each of these subsets could then be considered a rare disease (such as certain forms of cancer). Under the EU Regulation it is possible to obtain orphan designations for subsets of common diseases (although only subject to stringent conditions).

At the same time, advances in personalised medicine may add another layer of complexity to the current regulatory framework. Such developments may hold great potential for optimal tailoring of treatments to diseases and patients. However, they should not lead to unnecessary multiplications of rare diseases out of common diseases, to gain market exclusivity periods.<sup>42</sup> Especially in the field of oncology, we cannot but think that this is a practice that takes place there. There are of course many different genetic mutations one can identify, and on that basis, a new sub-set can be identified. In my view, that is a field that requires more attention than it receives today.

Another practice, which we have already discussed with the example we used above is indication-stacking. There are currently 22 orphan products authorised for two or more orphan indications on the EU market. These indications refer to distinct orphan conditions, and each

entitles the product in question to a period of market exclusivity. These periods may run in parallel, with their own start and finish dates.<sup>43</sup> If a product receives an authorisation for an additional indication or indications, it is assigned a new period of exclusivity for that specific indication. For the reasons we have explained above, this may present issues for generic market entry, as the web of different indications and orphan drug products with those overlapping indications on the market can present obstacles for generic entry. That is even more the case if the generic products could be prescribed cross-label for indications which are still under market exclusivity.

Sub-setting and indication stacking have led to complex strategies used by pharmaceutical companies to optimise exclusivity and delay generic entry. Let us analyse a couple of examples to see how these strategies have played out.

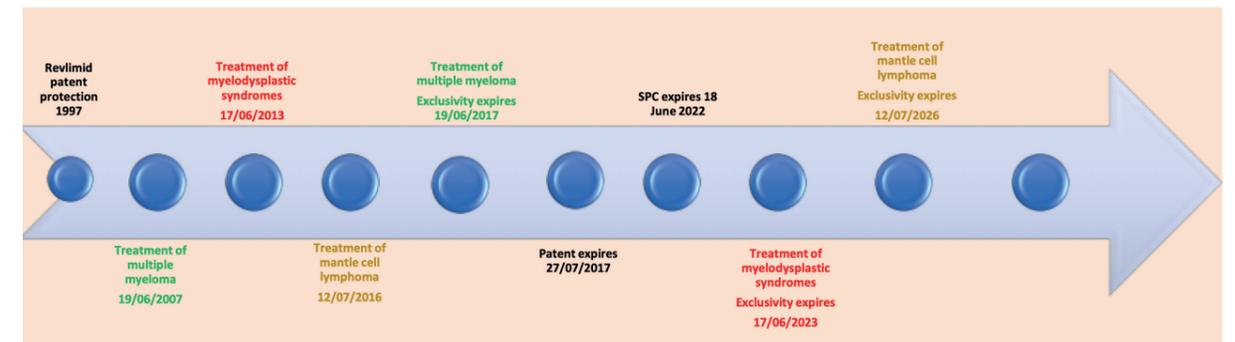
The orphan drug Revlimid® was approved for the treatment of multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma, subject to certain conditions regarding the patient’s previous treatment. Revlimid® contains the active ingredient Lenalidomide and is developed and marketed by Celgene. The exclusivity covers a combination of patent and SPC protection, and multiple MA’s, covering different orphan drug indications, each leading to a separate period of 10 years orphan drugs market exclusivity.

Revlimid®<sup>44</sup> obtained patent protection in 1997 and different MA’s for orphan drug indications. The patent expired on 27 July 2017, and the SPC expired on 18 June 2022. A follow-up patent for the polymorph form of Lenalidomide got invalidated and is no longer relevant.

The following orphan drug designations and MA’s have been granted for Revlimid® in Europe (each accompanied)

- Orphan market exclusivity for “Treatment of multiple myeloma” (designation EU/3/03/177) started on 19/06/2007 and ended on 19/06/2017.
- Orphan market exclusivity for “Treatment of myelodysplastic syndromes” (designation EU/3/04/192) started on 17/06/2013 and will expire on 17/06/2023.
- Orphan market exclusivity for “Treatment of mantle cell lymphoma” (designation EU/3/11/924) started on 12/07/2016 and will expire on 12/07/2026.

Figure 2:



As can be seen from the above, there are multiple MA’s for orphan drug indications, and each of those generates a separate ten years market exclusivity period (and the last orphan drug MA being granted in 2016). Consequently, market exclusivity for the drug will end in 2026, four years after the SPC based on the basic patent filed in 1997 has lapsed. This shows that a combination of patent and SPC protection, and a very strategic use of the possibility to accumulate market exclusivities for new orphan drug MA’s allows to extend exclusivity protection from 1997 to 2026 (which is almost 30 years from the filing date of the basic patent, being the first exclusivity date for the drug).

A second example is Glivec. On 7 November 2001, the Commission granted Novartis a marketing authorisation for imatinib under the commercial name Glivec for the treatment of adult patients with CML in chronic phase after failure of interferon-alpha therapy, or in accelerated phase or blast crisis. Subsequently, the Commission extended the terms of that marketing authorisation to cover other orphan conditions. Pursuant to Article 8 of Regulation No 141/2000, the period of exclusivity enjoyed by Glivec expired on 12 November 2011.

On 22 May 2006, the Commission designated and registered as an orphan medicinal product nilotinib, a medicinal product for the treatment of CML, which was sold under the commercial name Tasigna and developed by the holder of the marketing authorisation for Glivec. In the course of the marketing authorisation procedure for Tasigna, that holder indicated to the EMA that it consented to authorisation being granted for the marketing of that similar medicinal product for the same therapeutic indications as those covered by the marketing authorisation granted for Glivec, in accordance with Article 8(3)(a) of Regulation No 141/2000. On 19 November 2007, the Commission adopted a decision authorising the marketing of Tasigna for the treatment of adult patients with CML in chronic phase and accelerated phase, with resistance or intolerance to prior treatment involving Glivec. On 20 December 2010, the Commission extended the terms of that marketing authorisation to cover the treat-

ment of adult patients with newly diagnosed CML in chronic phase.

On 5 January 2012, Teva Pharmaceuticals Europe BV applied on behalf of Teva Pharma BV for authorisation to place on the market a generic version of Glivec. That application referred, inter alia, to certain CML therapeutic indications covered by the marketing authorisation granted for Tasigna.

The EMA refused to grant that application, in so far as it covered the CML therapeutic indications for which Tasigna enjoyed marketing authorisation, on the ground that those therapeutic indications still enjoyed market exclusivity protection under Article 8(1) of Regulation No 141/2000.<sup>45</sup>

Imatinib had been patented by Novartis in 1993. Taken that the first MA was granted in November 2001, the SPC for the patent lapsed in 2016,<sup>46</sup> and there was an entitlement to a one-off six months SPC extension based on an approved Paediatric Investigation Plan (PIP).<sup>47</sup>

Even though the market exclusivity for Glivec expired on 12 November 2011, the follow-up product Tasigna was still under market exclusivity at that time (which has lapsed in November 2017). Novartis withdrew Glivec product from the orphan register, however, in 2012. The reason for that was that it wanted to file for a six months paediatric extension of the SPC granted for the basic patent. Under the orphan drug system, it is not possible to file for a paediatric extension of an SPC for a patent.<sup>48</sup> Withdrawing Glivec from the orphan drug register could be done without much harm, as there was still market exclusivity for Tasigna until November 2017, and as a two years paediatric exclusivity was also obtained, until November 2019. In doing so, Novartis could kill two birds with one stone. It was capable of obtaining six months SPC extension based on its basic patent, whilst at the same time still retaining orphan drug market exclusivity for a similar medicinal product, i.e., Tasigna, for overlapping medical indications. This strategy optimised its exclusive rights position, delaying generic entry.

<sup>38</sup> A. DENIS, L. MERGAERT, C. FOSTIER, I. CLEEMPUT, S. SIMOENS, ‘Issues Surrounding Orphan Disease and Orphan Drug Policies in Europe’, [2010] *Appl Health Econ Health Policy*; 8 (5): [343-350] 344.

<sup>39</sup> W. YIN, ‘R&D policy, agency costs and innovation in personalized medicine’ [2009] *J. Health Econ.*, 28: 950-62.

<sup>40</sup> European Medicines Agency. COMP report to the Commission in relation to article 10 of regulation 141/2000 on orphan medicinal products. London: European Medicines Agency, 2007.

<sup>41</sup> Technopolis Report 2018, p. 102.

<sup>42</sup> COMMISSION STAFF WORKING DOCUMENT, 2020, p.68.

<sup>43</sup> COMMISSION STAFF WORKING DOCUMENT, 2020, p.68.

<sup>44</sup> Figure 2 represents the sequence of events in a timeline.

<sup>45</sup> Taken from paragraphs 9-14 of C-138/15 P, *Teva Pharma BV and Teva Pharmaceuticals Europe BV v. European Medicines Agency (EMA)*, ECLI:EU:C:2016:136.

<sup>46</sup> Using the calculation formula laid down in Art. 13 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 [OJ L 152, 16.6.2009, p. 1-10].

<sup>47</sup> Art. 36(1) of Regulation [EC] No 1901/2006 on medicinal products for paediatric use and amending Regulation [EEC] No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation [EC] No 726/2004. See also Art. 13(3) Regulation 469/2009.

<sup>48</sup> See Art.36 Regulation 1901/2006 (Paediatric Regulation).

An overview of the various MA's and market exclusivity periods can be found below:

Glivec, Imatinib (MA number EU/1/01/198):

- Orphan market exclusivity for "Treatment of chronic myeloid leukaemia" (based on designation EU/3/01/021) started on 12/11/2001. This orphan market exclusivity has ended on 12/11/2011
- Orphan market exclusivity for "Treatment of malignant gastrointestinal stromal tumours" (based on designation EU/3/01/061) started on 27/05/2002. This orphan market exclusivity has ended on 16/04/2012 (withdrawal of orphan drug status).
- Orphan market exclusivity for "Treatment of acute lymphoblastic leukaemia" (based on designation EU/3/05/304) started on 18/09/2006. This orphan market exclusivity has ended on 16/04/2012 (withdrawal of orphan drug status).
- Orphan market exclusivity for "Treatment of dermatofibrosarcoma protuberans" (based on designation EU/3/05/305) started on 18/09/2006. This orphan market exclusivity has ended on 16/04/2012 (withdrawal of orphan drug status).
- Orphan market exclusivity for "Treatment of chronic eosinophilic leukaemia and the hypereosinophilic syndrome" (based on designation EU/3/05/320) started on 01/12/2006. This orphan market exclusivity has ended on 16/04/2012 (withdrawal of orphan drug status).
- Orphan market exclusivity for "Treatment of myelodysplastic/myeloproliferative diseases" (based on designation EU/3/05/340) started on 01/12/2006. This orphan market exclusivity has ended on 16/04/2012 (withdrawal of orphan drug status).

Tasigna, Nilotinib (MA number EU/1/07/422):

- Orphan market exclusivity for "Treatment of chronic myeloid leukaemia" (based on designation EU/3/06/375) started on 21/11/2007. This orphan market exclusivity expired on 21/11/2017. An additional two years paediatric market exclusivity was obtained, which expired on 21/11/2019.

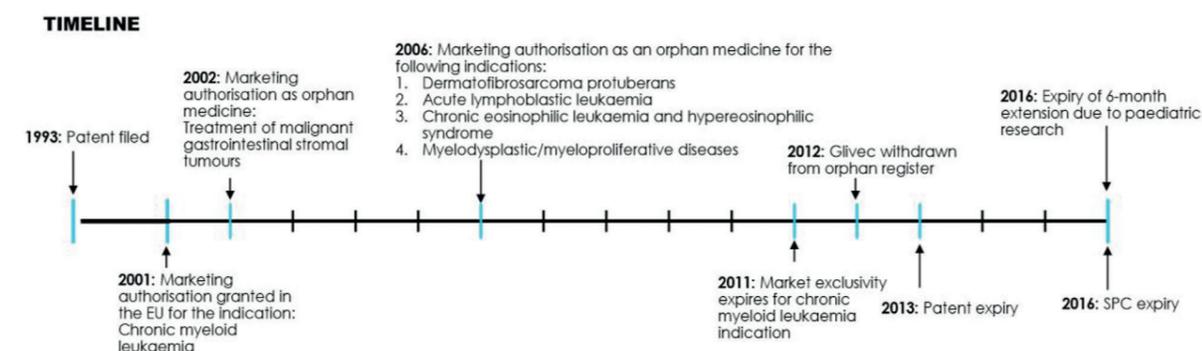
Figure 3:<sup>49</sup>

For Imatinib, Novartis would have been entitled to marketing exclusivity until 16 April 2016 (with a first MA date on 12 November 2001, which would have implied an almost 15 year exclusivity period. It withdrew the orphan drug status for Imatinib as it had a follow-up product, Tasigna, which still benefitted from exclusivity protection until 2019 (including the market exclusivity paediatric extension of 2 years). In other words, they could invoke Tasigna against generic entry in respect of marketing exclusivity for the active substance, whilst they could focus for Imatinib on the SPC paediatric extension (which is not compatible with the orphan drug paediatric extension).

What the above examples demonstrate is that pharmaceutical companies go at extreme lengths to optimise exclusivity protection on the products they put on the market. That could be achieved by taking advantage of the accumulation of exclusivities which the orphan drug system allows, but also by strategizing which combination of exclusive rights provides them the best position. That could be achieved by dropping certain exclusivities if they would not be compatible with other exclusive rights (such as orphan drug paediatric exclusivity extension being incompatible with obtaining a six months paediatric SPC extension) whilst at the same time ensuring that there are follow-on overlapping products that still provide the maximum exclusivity protection under regimes which would otherwise be mutually incompatible within the same medicinal product. It could be argued that this has very little to do with using incentive mechanisms to bring much needed new products on the market, but more with optimising revenues and delaying generic entry.

It should be equally clear from the above examples that it is not difficult to imagine examples where sub-setting, combined with indication stacking where relevant, could be an appealing strategy to delay generic entry, because of the fact that market exclusivity periods could be accumulated.

Figure 3:



## 4 SUGGESTIONS FOR THE FUTURE

### 4.1 The problems

Sub-setting and indication stacking allow the accumulation of market exclusivities, and can delay generic entry, as the examples above have shown.

Some, however, have argued that there is no real problem with the accumulation of market exclusivities, as each exclusivity follows the other, and the orphan drug for which the market exclusivity has lapsed becomes available for generic entry at no risk. Indeed, the argument is often used that the potential harm done by cumulative MA's for different orphan indications (which comes with each of their own ten years orphan drug market exclusivity) is limited, as after the market exclusivity for each of the orphan drug MA's has lapsed, generics can enter the market with generic versions of the drug for those indications which are no longer under market exclusivity.<sup>50</sup>

This line of argumentation is in my view ill-conceived, and is likely inspired by a lack of expertise in other areas of exclusive rights for pharmaceuticals. That argument overlooks the fact that generics can continue to be hampered if the drug formulation remains the same for each of those different orphan drug indications. If that is the case, physicians may prescribe the generic version of the orphan drug cross-label (or even off-label) for those indications which are still under market exclusivity. That can and will lead to scenarios very similar to the ones we see in the context of second medical use patents, which I will need to briefly address in what follows.

The drafters of the European Patent Convention (EPC) did not allow for patent protection for medical treatment methods,<sup>51</sup> as this was deemed to be not in conformity with societal views that physicians should not be hindered by patents when they chose or carried out a treatment method<sup>52</sup> (or diagnostic method on the human body or

surgical method for that matter).<sup>53</sup> Pharmaceutical products and medical instruments were on the other hand perfectly deemed patentable.

They did, however, provide for the protection of medical uses of an existing pharmaceutical compound,<sup>54</sup> thereby creating an exception to the strict novelty requirement under patent law.<sup>55</sup> Indeed, a first basic principle of patent law is that one can patent a new chemical entity as such as long as it does not form part of the state of the art. The drafters only provided for patent protection for the first medical use of an existing compound in the wording of the 1973 version of the EPC.<sup>56</sup> Under the literal wording of the EPC 1973, it was possible to obtain purpose limited product protection for the first medical use of an already existing drug. Such patent claim would typically read as "product X for the use as a medicament". It will immediately be understood that this is a very wide claim indeed, covering ALL medical applications of a known substance.<sup>57</sup> As a matter of practice, in virtually all cases, the claim is part of the patent which claims the chemical entity as such.

<sup>49</sup> Figure 3 is taken from the COMMISSION STAFF WORKING DOCUMENT, 2020, p 69.

<sup>50</sup> See COMMISSION STAFF WORKING DOCUMENT, 2020, p.68: "While overlapping or consecutive periods of market exclusivity can delay generic entry and may block the development of generic orphan medicines, they cannot prevent generic entry altogether, as each exclusivity period is tied to a specific orphan indication. A manufacturer willing to produce and market a generic version of an orphan medicine once the first market exclusivity period has expired is entitled to do so."

<sup>51</sup> In the US, medical treatment methods are perfectly patentable.

<sup>52</sup> See G 2/08, Dosage regime/ABBOTT RESPIRATORY, OJ EPO, 2010, 456, reasons 5.3.

<sup>53</sup> Art. 52(4) EPC 1973, Art. 53(c) EPC 2000: Article 53(c) EPC2000: "European patents shall not be granted in respect of: [...] (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human

or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods." For more details, see, S.J.R. BOSTYN, 'Medical treatment methods, medical indication claims and patentability: A quest into the rationale of the exclusion and patentability in the context of the future of personalised medicine', [2016] IPQ, 203-230, [hereinafter BOSTYN, IPQ, 2016b].

<sup>54</sup> For more details, see, BOSTYN, IPQ, 2016a; E. VENTOSE, Medical Patent Law – The Challenges of Medical Treatment (Edward Elgar Publishing, Cheltenham, 2011); F-E HUFNAGEL, 'Der Schutzbereich von Second Medical Use Patente' [2014] Gewerblicher Rechtsschutz und Urheberrecht (GRUR) 123-127; P. MEIER-BECK, 'Patentschutz für die zweite medizinische Indikation und ärztliche Therapiefreiheit', in, [2009] GRUR, 300-305; D. THUMS, 'Patent Protection for Medical Treatment – A Distinction Between Patent and Medical Law', [1996] International Review of Intellectual Property and Competition Law (IIC), 423 et seq.; H.

SCHACHT, Therapiefreiheit und Patentschutz für die weitere medizinische Indikation, (Nomos Verlagsgesellschaft, Baden-Baden, 2014); E.-M., MUELLER, Die Patentfähigkeit von Arzneimitteln. Der gewerbliche Rechtsschutz für pharmazeutische, medizinische und biotechnologische Erfindungen (Springer-Verlag, Berlin Heidelberg, 2003).

<sup>55</sup> See Art. 54 EPC.

<sup>56</sup> Article 54(5) EPC1973 reads: "The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art." Under the EPC2000, the almost identical provision is now in Article 54(4)."

<sup>57</sup> SCHACHT has probably rightly so criticised the very broad scope of those first medical indication claims, see, H. SCHACHT, *op.cit.*, p. 260-267.



What now if there was a situation where one invented yet another medical indication of an existing drug, for instance assume that someone invents that a drug can be used for the treatment of a certain condition? And what about the situation where another party (or for that matter the same party) invents yet another use of that same substance, for instance that the drug can be used for the treatment of yet another condition?<sup>58</sup> There was nothing in the statute about that eventuality.

Very quickly after the EPC entered into force, pharmaceutical companies argued that absent protection for further medical uses of an already patented or known substance, innovation into and development of medicinal products would be stifled, arguing that research into developing these new applications of existing drugs was expensive and laborious and deserved to be shielded from immediate copying by competitors if this type of research which was claimed to be of much benefit to society were to be continued. Whether that was a wise decision is not a matter for this article.<sup>59</sup>

Case law eventually provided a solution and allowed also claims for what was then called second and further medical indications. Absent a statutory provision under the EPC1973, case law had to be inventive, and came up

with what was then called the “Swiss claim” according to which one could protect “the use of a substance X for the manufacture of a medicament for the treatment of disease Y”.<sup>60</sup> The Enlarged Board of Appeal (EBA) came in the seminal G 5/83 case<sup>61</sup> first to the conclusion that the EPC had not envisaged to exclude second and further medical indication patents, to devise then a claim formulation that would fit within the confines of the then EPC1973. As a Swiss claim formulation does not protect the product as such, it was allowable.

Most common types of second medical use patents cover those inventions relating to a novel group of subjects,<sup>62</sup> subpopulations (at least in some jurisdictions),<sup>63</sup> relating to a new route or mode of administration,<sup>64</sup> relating to a different technical effect and leading to a truly new application,<sup>65</sup> and those relating to a new dosage regime for an existing drug.<sup>66</sup>

At the occasion of the negotiation of a new EPC (now known as EPC2000), it was deemed useful to codify the patentability of second medical uses. A new provision was introduced to that effect, allowing now also product claims for second and further medical uses, as that would be in line with what was already in existence for the first medical use, and it would also allegedly do away with the complications which were experienced with the Swiss claims. This new provision hence specifically allowed purpose limited product claims for second and further medical indication claims, confusingly also in Art. 54(5) EPC2000 (the first medical indication claim principle now laid down in Article 54(4) EPC2000).<sup>67</sup> A typical claim under this new provision would read “product X for the use in the treatment of disease Y”. This type of claim is what is called a purpose limited product claim, i.e., it protects the product but the scope is limited to the specific purpose or function of the product as laid down in the patent.<sup>68</sup>

Understanding some of those basic concepts of patenting pharmaceuticals is necessary to understand the next step in the reasoning, and that is the issue of enforcement of such medical indication patents.

What is the problem here? Imagine the following

scenario. The pharmaceutical compound as such is no longer patent protected. That means that the compound can be lawfully put on the market by a generic company, absent any IP protection. Imagine now also that a patent for an earlier second medical indication for condition X is also no longer under patent protection, and is being supplied by one or more generic pharmaceutical companies. However, there is still patent protection for a further medical use of the same compound to treat condition Y. What now if a physician prescribes the generic drug for a patented medical use (in my example to treat condition Y), and the pharmacist dispenses the generic drug for that same patented use? Is there patent infringement and if so by whom? Even if the physician and the pharmacist might be infringers, the patent holder will have no immediate incentive to sue those for patent infringement. He might be more interested in suing the generic company. Without having the space to go into detail here, the conclusion is that the generic company is liable for infringement if it knows or should have reasonably known that at least some of the generic drugs he produces are going to be prescribed and dispensed for the use in a patented medical indication. In certain jurisdictions, a qualified foreseeability test is being applied, according to which the generic manufacturer would not be liable to damages if he can prove that he has taken all reasonable measures with a view to prevent that his generic products are being used for the patented medical indication. In others, liability could be limited to situations where the generic product is prepared and presented in a way that infringement is clear from the presentation.<sup>69</sup>

The case law is rather unclear however, on which measure would be sufficient, and as we speak there is still a lot of legal uncertainty around this thorny issue.<sup>70</sup> The choice made for a specific test and indeed the conclusion that there is infringement on the side of the generic company could potentially have far reaching consequences. In most cases, the generic company will struggle to prevent physicians prescribing cross-label (or even off-label) their generic drug for a patented indication. And liability could

arise by the mere act of the generic drug being prescribed and dispensed for a patented use. If the burden of proof for the generic company is so high that it becomes virtually impossible to avoid infringement, then the business model of generic companies comes under enormous strain. A generic company will always be aware of the fact that it is possible that its products will be prescribed and dispensed for a patented medical indication.<sup>71</sup> This could be because of a preferential use scheme that might be in place in a certain jurisdiction,<sup>72</sup> or other schemes that favour the prescription of generic drugs with a view to save costs for the national health care system. That might imply that it would become de facto impossible to avoid infringement, which makes the business model for generic companies no longer viable. In the years to come, this issue will eventually need to be sorted out, whether by the courts or by the legislature, who could also intervene to settle the matter.<sup>73</sup>

It is not difficult to see the immediate parallel with new orphan drug indications and accumulation of regulatory exclusivities. Indeed, reverting back to my first example I gave in this article, if product A has gained a 10 years market exclusivity for the treatment of condition X and subsequently obtains another 10 years of market exclusivity for the treatment of condition Y, there is an infringement risk for a hypothetical generic version of A for X during the exclusivity period of Y, assuming that the drug formulation has not changed. This is an identical scenario to what I explained above in the context of second and further medical use patents. Claiming that the stacking of market exclusivities for the same active substance does not have the potential of a negative effect on generic entry has clearly been demonstrated here to be a fallacy. That is also the reason why we need to remedy this problem sooner rather than later, so as to avoid falling into the same undesirable situation as we have now with medical use patents. In the latter area, we have decided not to think about those issues for the best of 30 years, and we now struggle to find a workable solution. We surely do not want to face a similar situation for orphan drugs.

<sup>58</sup> E.g., a drug that is used for the treatment of epilepsy, and it is later discovered and patented that that same substance can also be used for the treatment of pain.

<sup>59</sup> I have expressed some views on this in my, BOSTYN, IPQ, 2016a; BOSTYN, IPQ, 2016b.

<sup>60</sup> Reason for this rather complicated claim formula was that there were some stumbling blocks within the EPC that prevented the courts to come to a more elegant solution. In view of the fact that Article 54(5) EPC1973 only allowed to claim the first medical indication as a product, as we have seen above, a product claim was no longer possible. And according to Article 52(4) EPC1973, medical treatment methods could

equally not be patented. That had as a consequence that a claim covering the “use of a substance X for the treatment of disease Y” was equally not possible. A claim for the use of a substance is nothing more than a method claim, and the abovementioned claim would hence cover a medical treatment.

<sup>61</sup> G 5/83, Second medical indication/EISAI, OJ EPO, 1985, 60.

<sup>62</sup> T 19/86, OJ EPO 1989, 24; T 893/90 of 22 July 1993; T 233/96 of 4 May 2000.

<sup>63</sup> T 1399/04, Combination therapy HCV/SCHERING, decision de dato 25 October 2006; T 0734/12, Arthritis patients with an inadequate response to a TNF-alpha

inhibitor/GENENTECH, INC., decision de dato 17 May 2013.

<sup>64</sup> T 51/93 of 8 June 1994; T 138/95 of 12 October 1999.

<sup>65</sup> T 290/86, OJ EPO 1992, 414; T 254/93, OJ EPO 1998, 285; T 1020/03, OJ EPO 2007, 204.

<sup>66</sup> G 2/08, Dosage regime/ABBOTT RESPIRATORY, OJ EPO, 2010, 456.

<sup>67</sup> Art. 54(5) EPC: “Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.”

<sup>68</sup> For more details on the distinction between absolute and purpose limited product

protection, see, S.J.R. BOSTYN, Patenting DNA Sequences (Polynucleotides) and Scope of Protection in the European Union: An Evaluation, Luxembourg, European Communities, 2004, pp. 56–66 [hereinafter BOSTYN, EC Report 2004].

<sup>69</sup> See e.g., *Generics (UK) Ltd (t/a Mylan) v. Warner-Lambert Company LLC* [2015] EWHC 2548 (Pat) [10 September 2015]; *Warner-Lambert Company LLC v. Generics (UK) Ltd (t/a Mylan) & Ors* [2016] EWCA Civ 1006 [13 October 2016]; *Carvedilol II* (BGH, Case X ZR 236/01); *Östrogenblocker* [Case I-2 W 6/17] [5 May 2017]; *Dexmedetomidin* [Case I-2 U 30/17] [1 March 2018], (BeckRS 2018, 2410); *Fulvestrant, OLG Düsseldorf, Urt. v.*

9.1.2019 – 2 U 27/18, GRUR, 2019, 279.

<sup>70</sup> This could not have been evidenced better than with the recent UK Supreme Court decision in the *Warner Lambert case relating to pregabalin (Warner-Lambert Company LLC v. Generics (UK) Ltd (t/a Mylan) & Anor* (rev 1) [2018] UKSC 56 [14 November 2018]). Apart from the fact that the patent got invalidated on the basis of “plausibility”, the Lord Justices could not agree on which test should be used to determine infringement of a second medical use patent.

<sup>71</sup> In many cases this will even be materialised in that the generic company will operate under a so-called skinny-label, i.e., the product specification will make reference to

all conditions that could be treated with the generic drug, but it will exclude the patented uses from the label. For more details; see, BOSTYN, IPQ, 2016a, 151-201.

<sup>72</sup> Under a preferential use scheme, physicians could be stimulated or even be under an obligation to prescribe always a generic version of a drug if there is one, irrespective of whether there is patent protection for the drug for a specific condition or not. For more details, see, BOSTYN, IPQ, 2016a, 151-201.

<sup>73</sup> I refer to my 2016 publication to that effect, see, BOSTYN, IPQ, 2016a, 151-201.

Admittedly, it may take a while (as it also took for second medical use patents), but the problems are bound to arise at some point. The reason why it may take a while is that apparently around 70% of the orphan drugs on the market still have primary active patent protection, that is, patent protection for the molecule or biological product as such.<sup>74</sup> In the presence of those primary patents, there is in most cases no need to revert to market exclusivity, as in most cases that primary patent protection (with the additional of possible SPC granted) will outlast the term of the market exclusivity, and the patent will be used as the instrument for enforcement against third parties. It is, however, a question of time to wait until there is a situation where 1) there is no longer a primary patent and/or 2) patents have been invalidated, and the only exclusivity left is the orphan drug market exclusivity.

We appreciate that, as the total number of orphan drugs on the market is rather small (currently 131 products on the market in Europe), it is difficult to draw very firm conclusions. As said, there are currently around 22 orphan drugs on the European market with multiple indications, which represents a 17% of the total number of authorised orphan drugs. That makes it in practice not easy to evaluate the economic impact of some of the issues we discussed on the pharmaceutical market. That is even more so as many of the orphan drugs have rather modest turnover numbers. The European Commission Staff Working Document draws the conclusion that such a small percentage does not justify immediate statutory change. But the mere fact that it is at this stage not very easy to draw firm economic impact conclusions, should not be seen as an invitation to stop researching those practices and warn for their potential negative economic effects on generic entry. My concern is moreover also informed by the so-called “iceberg” effect, i.e., that this might very well be something that is slowly growing unnoticed, and at some later point in time, we will come to the realisation that we should have acted earlier, very

much alike what has happened with second medical use patents, where we have not realised soon enough the potential generic entry problems. The “iceberg” effect is a very plausible hypothesis indeed, as it is very likely that over time a smaller proportion of orphan drugs will still benefit from primary patent protection, and more orphan drugs will indeed be repurposed drugs. Moreover, personalised medicine has become a reality, and that means in practice more repurposing.<sup>75</sup> That is, once again, a parallel with the second medical use story in patent law.

#### 4.2 The solutions

Because it is better to act sooner rather than later, I propose in this article a range of solutions to tackle the issues of indication stacking and sub-setting or salami-slicing. As the solutions for both sub-setting and indication stacking are in my view, at least to some extent, different, I will make the proposals also in two different sub-sections.<sup>76</sup>

##### Sub-setting

As for sub-setting, a number of possible solutions can be conceived:

One is to cluster all subset diseases within one main disease, and let the exclusivity period cover all of them at the same time. In other words, there would be one 10 years period (provided one would consider a 10 years exclusivity period still the best option) covering all those subset diseases of a main disease. For instance, a main type of rare lung cancer would then cover all the subset varieties of that type of lung cancer. The benefit of this solution is clarity and simplicity, as it largely does away with cumulative exclusivities for subsets of a main orphan disease of a certain type. The drawback is that, by taking away almost entirely the potential of sub-setting as a means to gain exclusivity, it might go at the expense of R&D in those areas. Whether that is detrimental can be doubted, as sub-setting is often a means to artificially

“create” new rare diseases based on even deeper gene profiling.

The above solution is very much akin to introducing the concept of GMA for “regular” drugs to sub-setting. That would imply that new indications would not be entitled to their own 10 years period, but could at best, for one new indication showing significant clinical benefit, a 1 year market exclusivity extension.

A second option could be to allow the “salami” to be of a certain size and to be “sliced” up a limited number of times. One could for instance think of a scenario where the applicant could only gain exclusivity protection for 2 or 3 subsets. Any further sub-setting would be without the benefit of an additional exclusivity.

A third option could be to allow sub-setting with exclusivity periods. But each of the subsets would only gain a shorter period of exclusivity, which could for instance be 3 years. That would still provide an incentive, but would have a much less negative effect in terms of delay for generic entry. That option could be combined with option 2, and should perhaps preferably be combined with option 2.

A fourth option in the context of sub-setting is to allow it under any of the above options, but to legislate specifically that the holder of any subsequent exclusivity period will not be entitled to sue for infringement against a third party who sells products that are not brought to market for the still protected indications (skinny labelling), but which could be prescribed for the protected use, save as for one exception. That exception would be that the third party deliberately markets the product for the protected indication.

##### Indication stacking

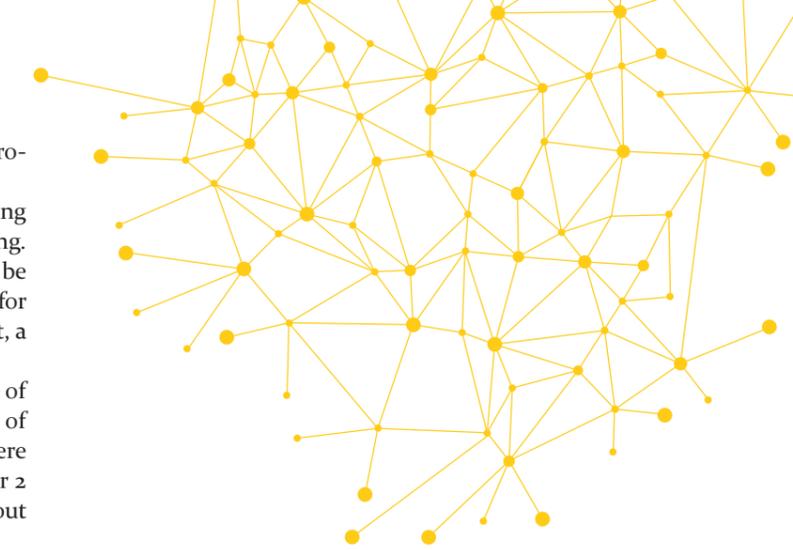
In relation to indication stacking, we also present a number of options. Indication stacking can take place in the context of sub-setting, but that does not necessarily have to be the case, as one could conceive repurposing the active substance to a rather different disease.

To the extent that the indication stacking takes place in the context of sub-setting, the options discussed below will indicate the consequences.

Option 1 could be to copy the system for “regular” drugs, and introduce the concept of GMA also for orphan drugs. That would imply that new indications would not be entitled to their own 10 years period, but could at best, for one new indication showing significant clinical benefit, a 1 year market exclusivity extension.

The benefit of this solution is clarity across the spectrum of pharmaceutical products. The drawback is that it might take away incentives for companies to invest in R&D in repurposing drugs for new orphan diseases.<sup>77</sup> As I have already explained, I do not think that there would be negative consequences in the case of indication stacking in the context of sub-setting, for the reasons already explained above in the context of sub-setting.

A second option could be to allow indication stacking for the same or similar pharmaceutical product, but each of those new indications will only be allowed a shortened period of exclusivity. That could for instance be 3 years.



The first orphan indication of an already existing or new active substance would be entitled to 10 years of market exclusivity, but each subsequent one only 3 years.

If indication stacking takes place in the context of sub-setting, this could be combined with a limitation to the number of subsets that create entitlement to an additional exclusivity period.

A third option could be to reduce the base period of 10 years for all orphan drugs. That could for instance be 5 or 7 years, and an extension could be obtained up to a maximum of 10 years in total upon providing evidence that no sufficient return on investment has been obtained within the period of 5 or 7 years. All further indications would then be entitled to the abovementioned 3 years. Alternatively, further indications would not gain any additional exclusivity period, in line with the GMA concept. Once again, if indication stacking takes place in the context of sub-setting, this could be combined with a limitation to the number of subsets that create entitlement to an additional exclusivity period.

A fourth option would be to take inspiration of the “salami slicing” scenario. Indication stacking with accompanying exclusivity periods would be allowed, but only for a limited number of indications. Once the “quota” has been exceeded, no further exclusivity could be obtained. The drawback of this solution is that it could disincentivise R&D and marketing of new orphan indications. If the indication stacking is in the context of sub-setting, granting no further exclusivity is without harm, as explained earlier. But if the new indication is not in the context of sub-setting, then there is the risk that companies will not have sufficient incentives to carry out research into new orphan drug indications.

A fifth option in the context of indication stacking is to allow it under any of the above options, but to legislate specifically that the holder of any subsequent exclusivity period will not be entitled to sue for infringement against a third party who sells products that are not brought to market for the still protected indications (skinny labelling), but which could be prescribed for the protected use, save as for one exception. That exception would be that the third party brings the product to market and/or deliberately markets to product for the protected indication, in which case there would be liability for infringement and right to damages.

<sup>74</sup> COMMISSION STAFF WORKING DOCUMENT, 2020, Part 3/6, p. 139 ([https://ec.europa.eu/health/system/files/2020-08/orphan-regulation\\_eval\\_swd\\_2020-163\\_part-3\\_0.pdf](https://ec.europa.eu/health/system/files/2020-08/orphan-regulation_eval_swd_2020-163_part-3_0.pdf)). The document lacks a methodology explaining how this percentage was calculated. We know it is quite difficult indeed to link medicinal products as authorised with patents, and the risk for errors is considerable, as multiple patents may cover the same compound.

<sup>75</sup> See for an explanation of “personalised medicine” and the link with repurposing my, S.J.R. BOSTYN, IPQ 2016a, 153 et seq.

<sup>76</sup> One could ask questions about the discretionary periods of protection provided in this list of options. All statutory exclusivity

periods are to some extent discretionary. For instance, the US orphan drug system provides a statutory market protection period of 7 years, whilst the European system provides a period of 10 years. The justification for this difference is, at least according to some, only explained as a desire to provide a more competitive exclusivity than the US system (see, European Union Review of Pharmaceutical Incentives: Suggestions for Change, Medicines Law and Policy, June 2019, p. 47: <https://medicineslawandpolicy.org/wp-content/uploads/2019/06/MLP-European-Union-Review-of-Pharma-Incentives-Suggestions-for-Change.pdf>). As the statutory exclusivity periods do not seem to have a firm basis in

science, the solutions provided in this article suggest exclusivity periods which seem reasonable and fair, even though admittedly not founded in science.

<sup>77</sup> There is of course always the patent system to protect those new indications, provided all patentability requirements can be fulfilled.

A sixth proposal is to introduce the same concept of what is the same marketing authorisation holder as we know for “regular” drugs. It is under the orphan drug system possible to give consent to a third party to bring on the market a similar medicinal orphan drug product for the same medical indications, and that consent will trigger in itself a new 10 years period of exclusivity.<sup>78</sup> For example, Novartis Germany could in that connection give consent to Novartis Switzerland, and a new 10 years exclusivity period will be triggered. Leaving aside the absence of cumulative exclusivity periods under the “regular” drug system, the definition of marketing authorisation holder is also defined broadly:

“An ‘applicant’ and ‘marketing authorisation holder’ can be a physical or legal entity. However, for the purposes of the application of the pharmaceuticals rules, having a distinct legal personality does not necessarily entail that each entity can be considered as a distinct applicant or marketing authorisation holder to the other one. In particular, it is noted:

- Applicants and marketing authorisation holders belonging to the same company group or that are controlled by the same physical or legal entity are to be considered as one entity.
- Applicants and marketing authorisation holders that do not belong to the same company group and are not controlled by the same physical or legal entity are to be considered as one applicant/marketing authorisation holder if they have concluded tacit or explicit agreements concerning the marketing of the same medicinal product for the purposes of the application of the pharmaceuticals rules regarding that medicinal product. This includes cases of joint marketing but also cases where one party licenses to the other party the right to market the same medicinal product in exchange for fees or other considerations.”<sup>79</sup>

By using a similar broad definition in the area of orphan drugs, one would fundamentally take away the incentive that different subsidiaries give each other consent (triggering a new 10 years exclusivity period), that holdings would do the same with subsidiaries, or that there would otherwise be an agreement between two companies. I do not see fundamental drawbacks to the research incentive system by doing so.

A seventh option is to replace exclusivities for new indications with a transferable voucher system. Such a voucher would allow the holder of the voucher (which provides a temporary market exclusivity) to sell it to an interested party and gain capital in return, which can be invested in further R&D. Transferable vouchers present problems though. It is very likely that they will be used so as to provide additional market exclusivity to block buster drugs (as such use will most likely generate the highest income for the transfer of the voucher), which in turn implies a further delay of generic entry for such block buster drugs. In that sense, I am myself quite sceptical towards the added value of transferable vouchers.

## 5 CONCLUSION

In this article, I have demonstrated that the orphan drug system is in need of amendment. This is in particular the case for the practices of sub-setting and indication stacking. The main argument to delay action in this regard that the percentage of indication stacking cases is relatively small (17%) is not convincing in my view, as we have seen also with second medical use patents that it takes often a very long period during which the “iceberg” grows, and once the size of the problem becomes apparent, the damage caused is often already considerable.

In order to avoid the negative effect of the abovementioned “iceberg” phenomenon, I have made a wide range of proposals for change. In my view, action must be taken sooner rather than later. Regulating for the future is better than remedying the past.

With regard to sub-setting, proposals range from taking away all further exclusivities after the “base” period of 10 years for any further subset to grant only short periods of exclusivity for a limited number of subsets (smaller salami with defined size slices).

In the context of indication stacking (which can go hand in hand with sub-setting, but does not need to), proposals range from introducing the GMA concept also for orphan drugs, de facto eliminating stacking of exclusivities, to also limiting the number of indications that can attain an additional exclusivity period of a limited duration.

We have finally also brought up the idea of reducing the base period of 10 years to for instance 5 or 7 years, with the possibility to gain an extension totalling 10 years provided it can be evidenced that no reasonable return on investment has been achieved within the base period. New indications could then 1) gain no additional exclusivity periods (in line with the GMA concept), or 2) attain a limited exclusivity period of for instance 3 years.

The purpose of the present article was to provide a document for further informed discussion in the process of reviewing the orphan drug exclusivity system in Europe. I hope that my proposals will indeed lead to such a fruitful discussion, and that action is taken by the European Commission to make the orphan drug system more performant, but at the same also take into account the interests of patients to get access to reasonably priced orphan drugs with the highest possible degree of competition between providers. To that effect, generic entry delay strategies should be a policy priority.



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<sup>78</sup> See Art. 8(3) Regulation 141/2000/EC: “By way of derogation from paragraph 1, and without prejudice to intellectual property law or any other provision of Community law, a marketing authorisation may be granted, for the same therapeutic indication, to a similar medicinal product if: (a) the holder of the marketing authorisation for the original orphan medicinal product has given his consent to the second applicant, [...]”

<sup>79</sup> NOTICE TO APPLICANTS, VOLUME 2A

Procedures for marketing authorisation  
CHAPTER 1 MARKETING AUTHORISATION,  
July 2019, section. 2.8, p. 14.

# Intellectual Property Rights and Economic Inequality: Theory and Evidence<sup>1</sup>

By Professor Keith E. Maskus

## 1 INTRODUCTION

I am pleased to be able to contribute to the special issue honoring Professor Marianne Levin. Marianne has long been a global leader in the legal analysis of intellectual property (IP) policy and has particularly been concerned with various socioeconomic ramifications of IP rights (IPRs). In that spirit, I offer this piece on a deeply important yet understudied aspect of IPRs: how do such rights interact with economic inequality, within and across nations? This complex question only recently has begun attracting attention by economists, despite massive concerns over growing inequality and its potential effects. In this paper I review the limited, yet substantive, theoretical and empirical studies of this issue. My objective is to explain how economists think about it, noting, for example, that there could be two-way causal impacts between IPRs and inequality.

There are several powerful and interrelated sources of growing income and wealth inequality, which operate to differing degrees in nearly all countries. Most impactful is the ongoing “skill-biased technical change” arising from rapidly improving information technologies, such as automation, robotics, and artificial intelligence, which may supplant the jobs of even medium-skilled workers.<sup>2</sup> Also important have been the falling transportation costs and trade and investment liberalization, supporting the offshoring of lower-skilled jobs from high-wage to low-wage countries, captured in the public imagination by the so-called “China Shock.”<sup>3</sup> Other key factors include the declining power of labor unions, increasing market concentration that shifts income toward highly skilled and productive workers and managers, and the inadequacy of educational systems at equipping workers with needed technical skills.<sup>4</sup>

Economists have largely ignored the possible roles played by IP protection in expanding inequality. Intuitive claims are readily made. For example, a sensible argument is that the exclusivity of IPRs raises returns to invention, innovation, and creativity, which are skill intensive. Relatedly, patents, copyrights, and other rights can establish temporary but strong pricing power in specific products and services, which correlates with rising market concentration, profits, and managerial compensation. Accordingly, stronger IP rights could help explain growing inequality. However, other influences push in the opposite direction. For example, IPRs raise product innovation and facilitate the diffusion of new goods and

technologies, expanding consumer gains from more varieties and lower prices. Moreover, these processes are linked to other policies, such as market opening and research and development (R&D) supports. Whether these outcomes increase or decrease inequality is an empirical question about which we have little clear evidence. Neither is much known about how growing inequality may change innovation incentives. In sum, the essential question of how inequality interacts with IPRs requires extensive economic research going forward.

## 2 BRIEF DATA OVERVIEW

The idea that inequality and IP rights are linked is intuitively plausible, in part because recent decades have seen notable increases in both on a global scale. For example, on a population-weighted basis, the Gini coefficient measuring the distribution of disposable income within countries rose between 1990 and 2015 by 10.2 percent among a group of 28 high-income countries (HICs), by 17.7 percent among 35 lower-middle-income countries (LMICs), and by 18.8 percent among 22 low-income countries (LICs).<sup>5</sup> It actually fell slightly for a group of 12 upper-middle-income countries (UMICs), though these had among the highest levels of inequality overall in the period. The weighted-average coefficient across all 97 countries in the sample rose by 14.6 percent. Marked increases in inequality were registered by the United States, with the Gini coefficient rising by 10.4 percent, and China, whose coefficient went up by 27.6 percent, among the highest of all nations. These are exceptionally large increases for a 25-year period.

Another measure, the share of gross national income (GNI) earned by the top 10 percent of households, tells a similar story.<sup>6</sup> Among the HICs, this top group increased its share of GNI from 31 percent to 35 percent, while among LMICs the share rose from 36 percent to 41 percent. This may seem small but, in fact, a five-point shift in the share of GNI is a large change by normal standards. Standing out again were the United States, with the top decile income share rising from 38.9 to 47.3, and China, with corresponding figures of 30.4 and 41.4. Indeed, this period saw a massive increase in inequality for China, India, and other middle-income countries.

Contemporaneous with this trend was a global expansion of the scope of IPRs, according to available metrics. For example, the celebrated Ginarte-Park (GP) index, a measure of the scope of legal protection of patent rights

across countries, rose on average by 91 percent among LICs, 182 percent among LMICs, and 103 percent among UMICs from 1990-2015.<sup>7</sup> Other indexes of IP rights followed a similar trend. These increases are due to the combined impacts of the TRIPS Agreement at the World Trade Organization, several preferential trade agreements with elevated requirements for IP protection, and other factors. As has been widely discussed,<sup>8</sup> even accounting for measurement errors and the lack of adequate enforcement mechanisms, this era saw the greatest and most globalized deepening of IPRs in history.

The fact that both inequality and the strength of IPRs have grown sharply begs the obvious question: Did countries with relatively stronger increases in the patent index see greater increases in inequality, at least as measured by the Gini coefficients? In fact, the answer is that the two measures bear little in common. Over this period, there was effectively no correlation between the GP index and the Gini coefficients on disposable incomes in the HICs, UMICs, and LMICs.<sup>9</sup> There was a positive and significant correlation in the lower-income economies, but it remained stable over time at around 0.2. In brief, simple correlations offer little evidence of any relationship between changes in measured patent rights and household income inequality, despite the remarkable changes in each variable individually.

## 3 ECONOMETRIC ANALYSIS OF WITHIN-COUNTRY INEQUALITY

### 3 A Macroeconomic data

Simple correlations do nothing to identify potential causal impacts of IP protection on inequality, or the reverse. International databases of Gini coefficients offer some room for statistical work on this issue, however. Two recent studies have used that data or similar figures to estimate the cross-country effects of IP protection on inequality, finding largely consistent results.

Adams (2008) was the first to incorporate IPRs empirically into a study of the determinants of international inequality. He assembled Gini coefficients compiled by the World Bank intermittently between 1985 and 2001 in a sample of 62 emerging and developing countries (EDCs). This data was regressed on various lagged independent variables that were argued to be important contributors to inequality. These variables included cer-

tain national globalization and policy variables, including trade openness, incoming foreign direct investment (FDI), secondary education rates, government consumption, an index of institutional quality, and GDP per capita. The scope of IPRs was measured by the GP patents index. The regressions found a consistently positive and significant effect of the GP index on subsequent inequality, with the main coefficient indicating that a one-unit increase in the patent index (on a five-point scale) would increase the average Gini coefficient by around 1.2 points (on a scale between zero and 100, though typically the relevant Gini range is between 30 and 60). Putting that in rough economic terms, a 20-percent strengthening of patent rights in the average EDC would raise income inequality by just over one percent. As for other key variables, a stronger institutional environment tends to reduce inequality significantly. One suggestion from these estimates is that if a country’s policymakers planned to strengthen its patent laws and were worried about possible impacts on income distribution, they might wish to accompany the IP reforms with more certainty about contract security, the rule of law, and related elements of institutional quality.



<sup>1</sup> This paper draws on Maskus (2022).

<sup>2</sup> See Brynjolfsson and MacAfee (2011) for a strong statement of this thesis.

<sup>3</sup> The phrase comes from Autor, Dorn, and Hanson (2013), who document these and other effects, kicking off a large literature on the labor-market impacts of low-wage imports.

<sup>4</sup> See Goldin and Katz (2008), Piketty (2014), and Acemoglu (2002) for seminal pieces on the sources of growing inequality.

<sup>5</sup> The Gini coefficient is an index of household income distribution, with values running from zero (all households have the same incomes) and 100 (one household has all the income). This data is from the Standardized World Income Inequality Database, described in Solt (2019). The computations mentioned here are from Maskus (2022), Table 1. The income groupings are those of the World Bank as of 1999.

<sup>6</sup> See Maskus (2022), Table 2.

<sup>7</sup> I am grateful to Walter Park for providing the data underlying the index. For these calculations, see Maskus (2022), Table 3.

<sup>8</sup> See, for example, Maskus (2012) and Deere (2009).

<sup>9</sup> See Maskus (2022), Table 4.

More recently, Saini and Mehra (2018) asked whether strengthened IP rights in the post-TRIPS era had affected income inequality, using a sample of 65 EDCs and developed economies over the period 1995–2009. These authors used the post-transfer Gini coefficients from the Standardized World Income Inequality Database (mentioned above) as the dependent variable in an econometric model similar to that in Adams (2008). Specifically, they regressed the post-transfer Gini coefficients on five-year averages of the GP index, openness to imports, inward FDI, GDP per capita, a measure of schooling, and indexes of political rights. They interacted the patent index with per-capita GDP to study whether the IPRs-inequality relationship was different for countries at different levels of economic development.

Remarkably, the findings were completely at odds with those of Adams (2008). In particular, the authors estimated that increases in the GP index tended to reduce the average Gini coefficient in developing countries, suggesting that stronger patent protection reduced income inequality. The authors speculated that this outcome reflected the fact that stronger IPRs tend to attract more inward technology transfer, which could raise the relative wages of lower-skilled workers in labor-abundant countries.<sup>10</sup> The coefficient on the interaction term of the patent index and GDP per capita was significantly positive, however, implying that the reduction in inequality was lower in rich nations. Indeed, for countries above a threshold income level the relationship could be positive, implying higher inequality with strengthened patent rights in developed economies. They interpreted this outcome to suggest that stronger patent laws may induce innovation in the latter group of countries, with rents to that activity favoring those with more technical and managerial skills. Unfortunately, the authors made no attempt to subject these broad conclusions to further empirical testing.

The results of these studies are intriguing if only because, for now, they stand as the only cross-country estimates available of the potential impacts of IP protection on internal income distribution. However, they find distinctly opposite impacts, suggesting that the correlation between the legal determinants of patent scope and inequality, as measured by Gini coefficients, is ambiguous, and its estimation may depend on the data used and the specifications set out. Moreover, it is important to note that cross-country studies using aggregated macroeconomic data are notoriously fragile, making it difficult to place much confidence in such estimates.<sup>11</sup> At this point,

the conclusion must be that no clear evidence has been unearthed about this basic question and much more work is necessary.

### 3 B Microeconomic Data

As noted earlier, economists have scrutinized a large set of hypotheses about the sources of within-country income and wealth inequality. Perhaps surprisingly, IP protection has been virtually ignored in this arena, except through intuitive claims about the role of IPRs in increasing the returns to R&D investments, which result ultimately in higher wages for skilled and technical workers. In this view, IPRs are another conduit for skill-biased technical change, which expands the gap between technically proficient engineers, entrepreneurs, and manager, at one end, and lower-skilled workers, at the other. Furthermore, patents, copyrights, trademarks, and trade secrets often are viewed as means of generating and protecting monopoly rents, which go disproportionately to these favored classes and shareholders.

Such claims are intuitively reasonable and find theoretical justification in various forms in the recent theoretical literature.<sup>12</sup> Rather than devote scarce space to reviewing these somewhat esoteric models, the primary point here is that fruitful empirical searches for inequality effects of intellectual-property protection should use microeconomic data involving innovative firms and agents at different parts of the income distribution. This approach is natural because patents exist at the firm level in specific locations, suggesting that carefully specified analysis could trace the impacts of private patenting on wage inequality within enterprises.

Two notable recent papers adopted this approach. First, Aghion et al. (2019) studied how firm-level innovation and patenting affects “top income inequality,” or increases in the income shares of the top one percent of US households. The paper modeled endogenous innovation decisions by firms that already own patents and earn monopoly profits versus new firms that innovate to own patents. In the model, innovation by either group raises the income shares of entrepreneurs and generates more income inequality. But only R&D investments by new firms increase social mobility, or the ability of entrants to enter the top income level. Such entry may be blocked by high innovation costs, including enforcement of existing patents, which reduces mobility. Although the model does not explicitly consider the role of stronger patent scope, presumably it would have offsetting effects. First,

broader patents should raise the returns on innovation and increase top income shares. Second, blocking entry should reduce the increases in inequality associated with more rapid entrepreneurship.

These ideas were tested empirically using state-level innovation data from 1975 to 2010. The authors accumulated data on the top one percent and top ten percent of income shares in all fifty states plus Washington DC. In that period, these high-income shares rose in every state, from an unweighted average of eight percent in 1975 to a maximum of 21 percent in 2007, before declining during the financial crisis. Additional data implied that income from entrepreneurship was largest in the top income groups in states with the highest patenting profiles. The income figures were combined with patenting data, including patent citations to construct quality measures. The authors regressed these top income shares across states on lagged patents and patent quality, controlling for business conditions, the importance of the financial sector, state GDP, and population, plus state and year fixed effects. In the regressions they found consistently positive and significant effects of patents and patent quality on the top one percent of incomes.

An obvious problem is that patenting may be driven by high incomes, which could be high for other reasons. To control for this potential endogeneity, the authors included each state’s representation on Congressional Appropriations Committees and other factors as instrumental variables. These specifications found similar impacts of patents on top income shares. In the best econometric specification, they found that a one-percent rise in patents per capita raised a state’s top income share by 0.17 percent. That is, patenting alone could explain 17 percent of the rise in the top-level income proportion across states. This effect was even larger in high-patent states, such as California. To understand the magnitude of this effect, the coefficients implied that if a state was to move from the bottom 25 percent of patents granted to the top 25 percent in the year 2000, there would be an increase in its top income share of about 1.5 percentage points, a substantial increase. Indeed, this effect could be underestimated because it did not account for the possibility that a successful inventor in a low-patent state would likely move to a high-patent state, among other factors.

A second study of note is by Bhattacharya et al. (2022). To summarize, these authors took advantage of a new Indian patent law, implemented between 2002 and 2005, to determine if the gap between manager wages and other

wages within firms differed by whether those firms owned patents before and after the legal change. They found consistently strong evidence of an increase in these wage gaps, which was more pronounced in high-technology industries. This evidence strongly indicates that firms transfer patent-based profits disproportionately to skilled and managerial workers within firms, raising wage inequality.

Such studies using microeconomic data are considerably more robust in econometric terms than the earlier macro-based analyses. They suggest that both patent reforms and patenting itself may increase income and wage inequality through intuitively familiar mechanisms. Many more such analyses, using other databases across countries, industries, and firms, would enrich this literature. It is also important to quantify how patents and patent laws contribute to growing within-industry market concentration and monopoly power across countries and how those rents have been distributed between worker types, managers, and shareholders.



<sup>10</sup> This point is taken up in more detail in the following section.

<sup>11</sup> See Levine and Renelt (1992) for an early critique, among many.

<sup>12</sup> See, for example, Chu (2010), and Pan, et al. (2015). Kiedaisch (2021) makes the interesting point that, in theory, the impact of IPRs on economic growth could depend on

the degree of income inequality.

<sup>13</sup> See Maskus (2022), Table 5. Baldwin (2016) cogently analyzes the sources of this relative change in incomes.

#### 4 EVIDENCE ON CROSS-COUNTRY INCOME CONVERGENCE

The prior sections considered the limited and contradictory findings about IPRs and economic inequality within countries, emphasizing the difficulties in estimating such impacts. There is, however, a second important dimension to consider. As noted above, the period since 1995 has seen a considerable expansion and globalization of IPRs around the world. At the same time, many EDCs have experienced relatively faster real GDP growth than have the developed economies. For example, using purchasing power parity exchange rates, with prices stated in 2017 US dollars, both LMICs and UMICs have experienced rapid growth in real GDP per capita between 1990 and 2015. On a GDP-weighted basis, the former group saw average annual growth of 3.9 percent and the latter registered 5.8 percent, compared with 1.9 percent in the HICs and 1.6 percent in the LICs.<sup>13</sup> An important stylized fact, therefore, is that income convergence between the LMICs and UMICs, on the one hand, and the HICs, on the other, has corresponded with relatively larger IPRs reforms in the former groups.

Have stronger IPRs played a role in this convergence? Again, it would be difficult to demonstrate with macroeconomic data that the former caused the latter, because many other factors could have driven both upward, making the correlation spurious. Examples include trade and FDI liberalization in the EDCs, increased opportunities for offshoring with vertical supply chains, and improved education and governance institutions. However, while largely correct, that point is misleading in at least one important context. Economic theory and empirical analysis find that, as a matter of microeconomic decision making, IP reforms in EDCs have attracted more technology flows, raising local productivity. The balance of this paper develops that argument. Note carefully, however, that higher real incomes from enhanced technology transfer do not necessarily imply more equal internal income distributions in EDCs, as the gains may have been acquired largely by the already well-off.

#### 4 A Technology Transfer and IPRs

There are three fundamental economic arguments for why effective IPRs, especially patent rights, may play a positive role in encouraging inward technology transfer, leading potentially to income convergence.<sup>14</sup> In this section I summarize these ideas, then turn to empirical evidence.

The first is the result of so-called product-cycle dynamics, referring to a continuous process of innovation in the advanced countries (the “North”) and knowledge transfer necessary to shift production in later stages to lower-wage EDCs (the “South”).<sup>15</sup> In the basic conception the stream of Northern innovation is exogenous, as is the rate at which Southern firms imitate new technologies. Ultimately, the South exports mature versions of new products to the North, where yet newer goods have been innovated, generating a cycle of new knowledge and diffusion.

These relative rates of innovation and diffusion drive changes in the global income distribution. An increase in the rate of innovation produces more Northern monopoly rents, which are paid to workers as higher wages. In contrast, a rise in the rate of imitation ends those monopolies and transfers production more rapidly to the South, raising wages there. The key income metric, the ratio of Northern to Southern wages, rises with innovation and falls with imitation. If innovation is sufficiently slow and imitation sufficiently fast, this ratio could approach unity, implying full income convergence. IPRs play a specific role in this process: stronger IP in the North expands innovation and protects wages there, while enhanced IP in the South raises imitation costs or forces firms to pay license fees, reducing wages there. Thus, stronger global IPRs worsen international income inequality in the basic model.

This simple proposition is the basis for concerns in developing countries about the potential impacts of IP reforms associated with TRIPS at the WTO. It featured in the first formal theory translating the product-cycle dynamics into an endogenous growth framework through purposeful innovation and technology transfer.<sup>16</sup> In a “quality ladders” framework, stronger patent protection in the South would support longer Northern monopolies, leading to reduced rates of both imitation and innovation, thereby limiting economic growth. In this view, the global policy harmonization demanded by TRIPS would be a serious mistake.

This result inspired an extensive literature extending the product-cycle model and IPRs in important directions. For example, subsequent models<sup>17</sup> posited that there are two forms of technology diffusion: imitation by Southern firms and information transfers through FDI and licensing by Northern multinational enterprises (MNEs). Foreign investment is responsive to Southern IPRs, especially in high-technology manufacturing and services, because MNEs feel more confident that they can transfer advanced information and know-how without losing them to local imitation. Licensing should expand with IP reforms for similar reasons and because patent

rights can reduce the costs of contracting. In consequence, FDI and licensing accelerate technology diffusion, raising Southern wages and reducing the North-South wage gap. Further, this process moves Northern labor from production to innovation, raising the latter. In this context, stronger IP protection in the South has offsetting effects: it slows down uncompensated imitation but enhances market-oriented technology transfer through FDI and licensing. The impact on the North-South income gap depends on circumstances.

Thus, whether IP reforms lead to income divergence or convergence is an empirical question. To date, there are no solid econometric studies of this issue for reasons already explained. However, there is consistent evidence that broader patent scope in EDCs tends to attract more FDI, licensing, and offshoring to those countries with affiliates and local firms that can incorporate technical information into domestic production.<sup>18</sup> The implication is that stronger IP protection likely has accelerated technology transfer and encouraged income convergence by shifting employment abroad from HICs to EDCs. In turn, the extensive international upgrading since TRIPS almost surely has reduced relative wages between workers in rich countries and the emerging countries through enhanced technology diffusion.

A second channel through which stronger IPRs may induce more technology transfer is its role in supporting the formation of international supply chains. The so-called “property rights” approach to the organization of firms argues that MNEs and local network partners operate as principals (multinational firms) and agents (local contractors).<sup>19</sup> The MNE and the input contractors bargain over how they will share the profits from production within the network. The contractor pays lower wages than the parent firm, which is the incentive for off-

shoring. However, once the contract is signed, the input supplier might save costs through shirking, which is more likely if the MNE cannot enforce its contract. Among other forms, shirking could involve stealing know-how or diluting the parent firm’s trademark and reputation. It follows that stronger IP rights in the contractor’s nation would raise the costs of shirking, making offshoring more likely.

The empirical prediction is that firms that potentially can produce high-quality inputs are more likely to be invited into a production network if their governments offer enforceable contract rights, including in the IPRs realm. Again, available evidence suggests that this is the case, for outsourcing locations at different stages of production, other things equal, are sensitive to local IP rights.<sup>20</sup> This logic applies as well to the recent emergence of R&D networks across countries within MNEs. Again, the implication is that EDCs with transparent IP rights are more likely to integrate with vertical production networks, a force for international wage convergence.

The third channel within which IPRs may lead to North-South income convergence may be labeled trade-induced innovation, or the possibility that trade and investment liberalization can push domestic firms to become more innovative and productive. Modern international trade theory emphasizes that market opening pushes resources into the most efficient enterprises, which raises labor productivity and wages in general, though with a bias toward those with greater skills. More fundamentally, when a country cuts its trade barriers, local firms must adopt globally efficient techniques to enter export markets. This tends to raise the relative wages of workers in such firms. Indeed, exporting firms and affiliates of MNEs typically pay significantly higher wages in EDCs than local firms.

<sup>14</sup> Hoekman, et al. [2005] offer further perspective.

<sup>15</sup> The product-cycle model was first explicated by Vernon (1966) and is a workhorse model in trade and global business studies.

<sup>16</sup> Helpman (1993).

<sup>17</sup> See, among others, Lai (1998), Glass and Saggi (2002), and Yang and Maskus (2001).

<sup>18</sup> A full review of this evidence is excluded for reasons of space. See Maskus (2012, 2022)

and Park (2008) for more discussion.

<sup>19</sup> The property-rights analysis of principal-agent problems was pioneered by Hart and Moore (1990) and Williamson (1985). It is a fundamental theory of the boundaries of a firm, analyzing conditions under which a firm would produce inputs in-house or outsource them to a contractor. It was extended to international outsourcing and IPRs by Antras (2003, 2005).

<sup>20</sup> For example, Canals and Sener (2014) found that US multinational firms in patent-intensive sectors significantly expanded their offshoring within their primary industries to emerging countries following substantial IPRs reforms.

<sup>21</sup> Bustos (2011).

<sup>22</sup> Aghion, et al. (2018).



Trade liberalization through tariff cuts and joining free trade agreements may also force more innovation on the part of domestic firms. As suggested above, such firms must lower costs to compete with more efficient imports or develop new products to enter export markets. Both processes require investments in R&D, new capital goods, and better management techniques. Argentina offered initial evidence for this spur to innovation in the wake of trade opening by a middle-income economy.<sup>21</sup> The author found that higher-productivity Argentine firms facing larger cuts in Brazilian tariffs after the implementation of MERCOSUR invested more in improved technologies. A second study<sup>22</sup> featured a theoretical model in which greater access to export markets increased the incentives of certain domestic firms to innovate. Specifically, high-productivity firms have the resources to invest more in R&D and develop new products, while low-productivity enterprises reduce their innovation spending. These predictions were borne out of using exporting and patenting data of French firms from 1994 to 2012.

The relationships between market opening and innovation are considerably more complex than suggested here, and much depends on local circumstances in each country. The preponderance of evidence, however, finds that increasing global integration has encouraged more innovation, at least in developed and higher-income emerging economies. These innovation responses, concentrated in high-productivity enterprises, likely have contributed to higher wage inequality across skill classes within reforming countries. At the same time, they are a powerful force toward international income convergence as defined here.

While these effects seem robust at this stage, available studies have not yet linked trade liberalization and IPRs in a serious study of induced innovation and global inequality. In principle, trade liberalizers with stronger IPRs may experience greater innovation impacts, at least as measured by formal metrics. This is an important area that remains open for research. Overall, however, these various channels support the view that IPRs reforms have contributed to international convergence, even as they may have exacerbated internal inequality within reforming economies.

## 5 CONCLUDING REMARKS

It seems intuitive and evident that IP protection is likely a force for rising economic inequality for a variety of reasons. However, a primary lesson from this paper is that establishing that causality is challenging, and systematic evidence is scarce. Cross-country macroeconomic regressions of Gini coefficients on available measures of IP protection find opposing evidence across specifications, which is not informative. At the same time, emerging econometric evidence using detailed microeconomic data suggests that firms engaged in more global patenting tend to have more unequal internal wages, even within occupational categories. These findings are suggestive but a long way from establishing a firm and generalizable relationship. To be sure, far more analysis is needed.

Another point made here is that IP reforms may accompany trade and investment liberalization, contributing to internal inequality, especially in EDCs. However, while the channels through which trade, FDI, and outsourcing through production networks can affect internal and external inequality, are reasonably well understood, there has been almost no empirical study of how IPRs may contribute. This also is a yawning hole in our understanding and needs to be rectified with additional study.

Finally, there is clear evidence that IP reforms have contributed significantly to increased flows of market-oriented technology transfer from technologically advanced countries to certain EDCs. Because these flows embody knowledge that can raise local productivity and transform the global structure of production, IPRs likely have had an indirect but substantially positive effect on raising average incomes in recipient EDCs relative to those in rich countries. This process of income convergence is a critical outcome of the globalized IP system but remains underappreciated and deserves far more analysis. Unfortunately, however, such flows have not materialized in poorer countries, whose incomes continue to stagnate in relative terms, despite their own reformations of intellectual property policy.

I hope that this chapter opens avenues for further research that will help sort out the underlying explanations for both these stylized outcomes and impacts on other, heretofore largely ignored, socioeconomic outcomes. I am sure that Professor Marianne Levin would agree that we have moved forward in our understanding but there are many hills left to climb.



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# The moral significance of intellectual property regulation

By Professor Mats Hansson

## ABSTRACT

*Fundamental ethical principles provide guidance for the protection and wider use of intellectual achievements. As regarding established rules for claims of authorship in scientific publications, use of intellectual property is not a matter of providing an open unregulated access but to honor the intellectual achievements while providing an avenue to wide application for promotion of innovation to the benefit of society. This is done through a balancing of different interests. In this article I examine some of the basic principles for this balancing task. A special concern in the discussion about intellectual property regulation has been the need to fit new scientific and technical innovations within the changing moral landscapes of different countries. Innovations must not offend what is considered "public order". I put this claim into perspective by demonstrating that this value laden concept needs to be adjusted in accordance to changing moral landscapes that often follow when new innovations become part of main stream technology and provide significant benefits.*

## OPENNESS ON FAIR TERMS FOR DISSEMINATION OF KNOWLEDGE AND INNOVATION

In popular views it may be believed that patenting and intellectual property regulation is a way of hiding new findings and methodological development in various areas from others. The contrary is in fact true and is of great moral significance. The following story told by a colleague in molecular biology at a Swedish university may illustrate the point. He was visiting a large biotech company and on his tour around the facility he saw that they used a new and very innovative method for analysis of biochemical compounds. He hadn't seen it before but it was a method that would be of great value for use also in his own laboratory. However, the company was big and didn't really bother about a patent in this case. His comment to his guide was: "Why don't you patent this method so that we can use it also in my lab"? Patenting is in this sense an instrument for providing open access to innovations, with the important addition *open and regulated access*.

Openness is a cherished value also in academic life with recent requirements from funding agencies to provide

open access of publications. It is important from a scientific point of view since a central requirement in science is that claimed results must be reproducible. Another scientist with sufficient skills must in principle be able to replicate the findings using the same kind of material and the same methods. However, also here it is a matter of open but not unregulated access. The same holds for sharing of data that have been used for the research. In biomedicine, sharing of data and bio-specimens is essential for the discovery, new knowledge creation and translation of various biomedical research findings into improved diagnostics, biomarkers, treatment development, patient care, health service planning and general population health. There is a growing international agreement on the need to provide access to research data sets to optimize their use and fully exploit their long-term value<sup>1,2,3</sup>.

Ideally, data should be made widely available to the most inclusive and ethically responsible research, but there is often resistance by institutions and individuals who fear that they will not receive recognition for their investment in collecting the data. Data is not freely floating around to just be picked. It is the result of systematic efforts requiring scientific accuracy regarding selection and use of methods, as well as resources and time. This feature is recognized in the existing research ethics rules and guidelines for authorship in academic journals. The International Committee of Medical Journal Editors recommend that authorship should be based on "substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work" (also known as the Vancouver guidelines for authorship)<sup>4</sup>. Regarding sharing of and access to data as well as biospecimens the following ethical principle have been suggested as guidance to the research community<sup>5</sup>.

1. Freedom of scientific enquiry: custodianship should encourage openness of scientific enquiry, and should maximize data and bio-specimen use and sharing so as to exploit their full potential to promote health.
2. Attribution: the intellectual investment of investigators involved in the creation of data registries and bio-repositories is often substantial, and should be acknowledged by mutual agreement.
3. Respect for intellectual property: the sharing of data and biospecimens needs to protect proprietary information and address the requirements of institutions and third-party funders.

From a laypersons perspective these principles are reflected also in intellectual property law<sup>6</sup>. A patent acknowledges the principle of attribution but protects at the same time openness and freedom of scientific enquiry. The exclusive right to exploit an invention is referring only to commercial use, leaving academic research and intellectual exploitation open for anyone. It may be seen as a vehicle for innovation and as a stimulation for open competition to look for alternative means to solve a problem, ideas that are intrinsic to science as well. Openness, whether through publication or patenting, is arguably also something expected by funding agencies, both governmental and private. They don't grant money for research in order for scientists to hide the results in the drawer. They should be used as widely as possible for innovation and social benefit.

## PUBLIC ORDER AND MORALITY

There is a well-known article in patent law pointing at the moral significance of a patent approval process. In the Swedish Patent Act (1967:837, 2020:541) this is formulated in Chapter 1, Article 1c, laying down that "a patent is not granted for an invention where the commercial exploitation would be contrary to public order or morality". Within the field of biotechnology and life science this has implied some challenges related to find out where to draw the line between what is in accordance with public order and morality, and what is contrary. It is well known that the moral landscape is in constant change in all societies, more and more rapidly due to new communication and information means that don't respect any national borders. In biotechnology and life science the situation is accentuated with scientists constantly breaking barriers on what was seen as possible. There are several stories where new discoveries have led to intense discussions about moral acceptability, and requests for legislation, including related to intellectual property regulation.

As described in detail by Marianne Levin, based on a report from the sixth Framework project in EU *Stem Cell Patents: European Patent Law and Ethics*, the exceptions regarding patentability based on the above clause have to be based on national constitutional and culturally accepted value systems.<sup>7</sup> It is regarded as self-evident that in a political democracy, people's values play an important role. Not only all legislation, but also other policy and regulatory decisions, presuppose some degree of anchorage in the values of the people. Despite this, values do not in themselves constitute good arguments, and from an ethical point of view, it is problematic to take these for granted. The reason is that one sometimes changes one's opinions after having acquired more information about the facts, or having perceived the kind of value conflicts which arise, when some value which one esteems is achieved while other values are denied. One perhaps discovers values which had passed unnoticed and undesirable consequences which had not been anticipated. One tends therefore to agree with George Henrik von Wright's idea that informed preferences should be taken more seriously than the preferences we actually happen to have at the

moment.<sup>8</sup> "To come into possession of, or experience some X which we wish, increases our welfare provided that we would wish this X if we were informed about the causal relations and consequences which hold both for the totality of which X is part and the totality where not-X is included instead of X" (*ibid.*, 7). von Wright speaks in this connection about people's individual preferences, but it ought to be possible to apply this reasoning also to collective political decisions, for example those which apply to the balancing of values at stake in association with regulation of life science research and biotechnologies.

An intrinsic requirement for moral assessment is that conclusions and advices are based on a close understanding and acknowledgement of scientific facts and realistic considerations of contexts for research or practice where ethicists and lawyers work closely together with scientists and practitioners. This implies that foresight analyses where current knowledge and practices are extrapolated in order to speculate about and discuss likely future scenarios is of limited value since there is no factual evidence available. There is also a tendency that foresight analyses focus more on disadvantages than advantages and that they are ultimately not able to balance ethical reflections between Dystopia and Utopia alternatives. New emerging technologies face specific problems due to their complexity or novelty. Gene therapy, preimplantation genetic diagnosis, whole genome sequencing or gene editing may be candidates in kind. They have all stirred intense ethical discussions when they first were presented in scholarly journals and at scientific conferences, or reported in public media. Some early research applications with these technologies were indeed premature and should have awaited better evidence but, after some progress and more scientific evidence about benefits and risks, most of them will belong to main stream medical science.

Gene therapy is an example of a promising new technology developed forty years ago. It met with quite some resistance, not the least from religious representatives. Some warned against Gene therapy as a way of "Playing God".<sup>9</sup> The term may be interpreted in two ways. First, it may convey an idea about the power of genetic intervention itself. It was claimed in the debate, during the late 1970's and the beginning of 1980's, that scientists now were on the threshold of understanding how the fundamental machinery of life works.<sup>9</sup> What was earlier



objects of awe and wonder were now perceived as objects under human control, one was "tampering with the basic building blocks of life". Second, it may convey an idea that genetic intervention may create new life forms, the consequences of which can neither be foretold, nor controlled. The objection of "playing God" could, however, easily be turned in another direction, as was done by a father, three of whose children suffered from a sickle disease. He said: "I resent the fact that a few well-meaning individuals have presented arguments strong enough to curtail the scientific technology which promises to give some hope to those suffering from a genetic disease. I have faith to believe that genetic therapy research, if allowed to continue, will be used to give life to those who are just existing... I, too, would like to ask the question, who do we designate to play God? Aren't those theologians and politicians playing God? Aren't they deciding what's best for me without any knowledge about my suffering?"<sup>10</sup> Forty years later there are several clinical trials with gene therapy ongoing, in particular for rare diseases where there are few or no treatment alternatives available. The technology is now moving into main stream medical science governed by ordinary regulatory frameworks for clinical trials, despite the fact that in the beginning it was by many conceived as being against "public order and morality".

One area of life science research that has been focus for intense discussions on patentability is the production and use of human embryonic stem cell lines. According to the referred article of the Swedish Patent Act "the use of human embryos for industrial or commercial purposes" is considered as contrary to public order and morality and, accordingly, excluded from patentability. This interpretation is reiterated in the official information from the Swedish, Intellectual Property Office (PRV): "Methods which use human embryos, such as the production of embryonic stem cells, are ... not patentable".<sup>11</sup> A common argument for excluding human embryos from patentability is that the recovery of stem cells from the embryos with necessity implies that they are destroyed, something

that would constitute a violation of the respect for life.<sup>12</sup> The argument is, however, dubious for the following reasons. Recovery of stem cells is only done using left-over cryo-preserved embryos in association with in vitro fertilization. These embryos will be discarded anyway and are treated as hazardous biological waste in the fertility clinics. They are voluntarily donated by the couples themselves who provide a written informed consent. To donate them for research and medical purposes is seen by these couples as a good alternative to just destroy and throw them away. It is also a fact that many countries, including Sweden, permits research on fertilized eggs up to day 14 of the development, a practice that also implies the destruction of the embryos (see LGI 2006:351).

A recent study among the Swedish general population showed that even those respondents who regarded the embryo as "potential life" were positive to the use of surplus embryos for a good medical purpose.<sup>13</sup> The context here was the use of human embryonic stem cells for the development of Advanced Therapy Medicinal Products (ATMP) in order to treat patients with Parkinson's disease. As for now, the etiology of Parkinson's disease is still unknown. There are no disease modifying therapies available for patients so therapy focuses on symptom relief by compensating for low brain dopamine levels. Commonly, patients' daily lives are increasingly affected over time by symptoms such as tremor, slow movements and balance problems. It is common to develop non-motor problems like depressive symptoms and later dementia. As the symptoms get worse with time, medicines are often given more frequently and device-aided therapies are introduced. It is not uncommon that patients suffer from side-effects of treatment, such as dyskinesia or behavioral problems. Parkinson's disease is one of the first examples of this kind of cell therapy that now is close to clinical application.<sup>14</sup> In general, respondents were positive towards the usage of embryonic stem cells to treat patients with Parkinson's disease, but the usage were conditioned and specific terms were demanded. Informed consent from both donors were required

and delicacy and sensitivity when working with embryos were needed.

It seems, in this case, as in many other instances related to the new developments in life science exemplified above, that views on "public order and morality" changes when there are clear (medical) benefits attained. Technological developments and value changes in society form the basis for the establishment of new social conventions. One may believe that saying no to new biotechnologies is the morally safe way to go but if important benefits and risks (e.g., related to staying at the level of currently available insufficient treatment) are at stake one is equally responsible both when saying no and saying yes, alluding here to von Wright's argument earlier. Taking these studies into regard the time seems to be ripe for reforming the patent law in order to stay better attuned to "public order and morality", assuming that it is the Swedish public order and morality that shall be taken into regard. It is the responsibility of legislators, judicial authorities and policy makers to closely monitor both the factual circumstances of new life science technologies and the constantly changing moral landscape of salient values. We cannot expect that they will always make the right decision, but we do expect that they will consider all relevant aspects of a case and that they will take and weigh up the arguments in their final judgement in a way which is reasonable with reference to the importance of the issue and the consequences which follow from their judgement.

It is clear also that, in this field as in many other developments of medical treatment, the involvement of the biotech industry and pharmaceutical companies is necessary in order to bring a research innovation all the way from the lab bench to clinical use. Even if academic partners may not be interested in seeking patent protection of their achievements it is essential also to make sure that this road is not closed for commercial partners approached later in the development process for collaboration downstream in order to attain a real patient benefit at the end.

## BALANCING THE SCOPE

A central component in all ethical and legal discussions is the need of reaching a balance between different values at stake and between different interest held by different stake holders. The requirement of balancing is well represented in the premises for ethical review of both animal and human subjects' research. According to the Swedish Act (2003:460) on ethical review for research involving human subjects the task of ethical review boards is to balance the scientific value of a research project against the risks which people acting as experimental subjects may run by participating in the experiment. I have elsewhere in some detail discussed the need of balancing privacy concerns against the interests related to providing new and improved treatment opportunities through medical science and will not reiterate that here.<sup>15</sup> As described above, scientific progress and innovation in the field of life science requires a wide access to both research data and personal data. Since human rights are often

referred to in connection to expressing the need to protect human interests in association with the use of personal data in life science development I will just make one point focusing on the balancing of privacy/integrity and the interests of making progress in medical science.

The use of personal data should stand in agreement with the European Convention for the Protection of Human Rights and Fundamental Freedoms, the Social Charters adopted by the Union and by the Council of Europe, the Charter of Fundamental Rights of the European Union (2010/C 83/02). The right of each individual to integrity within the fields of medicine and biology implies, according to these premises, a free and informed consent according to the procedures laid down by law (Article 3). The right of each individual to the protection of personal data concerning him or her is recognized (Article 8), implying that processing of such data requires consent of the person concerned or some other legitimate basis laid down by law, e.g., as laid down in GDPR, with reference to public interest. In addition to these autonomy rights, it is also acknowledged that the Charter of Fundamental Rights of the European Union also lays down rights of each individual to social security benefits and social services in cases of illness (Article 34), the rights of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices (Article 35). In this context the steering principles laid down in the United Nations Declarations of Human Rights (Article 27) also apply:

1. *"Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.*
2. *Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."*

Thus, balancing of different interests and rights need to be reflected in legislation and legal practice. This is well recognized in the intellectual property legislation, as described above. At one of the extreme ends, the intellectual property holder may want as far-reaching exclusive use of a product or method to be patented as possible. At the other end, society, e.g., patients and scientists, want benefits to be as freely available as possible. One example of this conflict of interests is the discussions related to use of human embryos for research. The example also highlights the need, both in ethical and legal analyses, to have a good grip on the factual basis.

The European Group on Ethics in Science and New Technologies (EGE) is an independent ethical advisory body of the President of the European Commission, founded in 1991. The EGE reports to the President and to the Commissioners as a whole. In 2002 the EGE evaluated the ethical aspects of patenting inventions involving human stem cells.<sup>16</sup> They argued that isolated stem cells, which have not been modified, do not, as products, fulfill

the legal requirements to be seen as patentable. Induced pluripotent adult stem cells may fulfil this requirement since they have been genetically modified. Genetical modification was one example given by the EGE. EGE claimed that one should distinguish among: (a) “stem cells freshly derived from an organ or tissue which have not yet been subjected to any modification and which are capable of being propagated as stem cell lines,” (b) “unmodified stem cell lines which refer to cultured lines of cells which have been propagated originally from freshly derived stem cells and which have not been modified in any other way. . . ,” and (c) “modified stem cell lines which refer to cultured lines of cells, propagated from stem cells or stem cell lines, which have been modified either by genetic manipulation, or by treatment that causes the cells to differentiate in a particular way” (*ibid*). Only the last kind of cells should be patentable according to EGE.

Genetic modification, as in the production of induced pluripotent adult stem cells, represents indeed a major scientific achievement and something that may be acknowledged in intellectual property protection. However, in discussions with stem cell scientists it became clear that already the act of producing a viable stem cell line requires extraordinary scientific skills and effort.<sup>17</sup> Also isolated embryonic stem cell lines are results of modification. The only “unmodified” human stem cells are those still present in the human body or embryo. Embryonic stem (ES) cells are isolated from in vitro fertilized (IVF) embryos that have been cultured in vitro up to the blastocyst stage. If used for infertility treatment, such embryos are transplanted into the uterus of a woman. If used for the derivation of an ES cell line, the blastocysts are explanted into a special culture medium and cultured in vitro for an extended period of time, generating a novel cell type that is not part of the blastocyst. Already, the act of placing a cell into a culture medium implies modification.<sup>18</sup> The isolation process does not select for pluripotency, just for survival, with pluripotency being a useful side product of the procedure. The result of adaptation to tissue culture is the outgrowth of cells that have no equivalent to cells in the embryo. Thus, an ES cell basically represents a cultural artifact. Based on these facts it has been argued that isolated embryonic stem cell lines may carry sufficient novelty, inventive step and potential for industrial application and be in principle patentable as products, besides patentability of the methods developed for their isolation and proliferation (*ibid*).

An important feature of intellectual property law is the requirement of balancing rights of exclusive use and the importance of producing common benefits for society. It is important to note then that patentability does not necessarily lead to broad patents. An example of this may be seen in relation to the WARF patent application. The United States Patent and Trade Mark Office issued a broad patent on December 1, 1998 claiming patent on primate ES cells, including human and on March 13, 2001, a second patent focusing on hESC.<sup>19</sup> The origins of the cell lines were two nonhuman species of primates, but the claim granted covered a larger group of primates, including humans. hESC made in another country become

subject to U.S. patent law if they were to be imported into the United States. As described above, the fundamental principle of a patent is to protect reasonable commercial claims and inventive achievements as a means to promote technological development and application of research into different sectors of society. The two WARF patents violated this principle by granting claims with an unreasonable scope leading to a situation that, in fact, may be detrimental to stem cell research. This story underlines the importance of balancing on behalf of patent authorities.

## CONCLUSION

Ethical consideration is about balancing different values and interests against each other. Intellectual property regulation is a vital means for open access and innovation, provided that one adheres closely to the scientific factual context and to the changing moral landscapes of societies. Open, but not unregulated access is the way forward.



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# Injunctions in the UPC and the principle of proportionality

By Prof. Dr. Ansgar Ohly

## I INTRODUCTION

The way towards a European patent judiciary is best characterised by the title of a Beatles song: it has been “a long and winding road”. But after many proposals, initiatives and setbacks the Unified Patent Court now finally seems to become reality. The tricky issue of whether the UK could still participate even after Brexit<sup>1</sup> has been solved – in a very unfortunate way, but it has been solved. The constitutional challenge in Germany has made a new implementation in the German Parliament necessary,<sup>2</sup> but the new implementing act reached the necessary two-third majority, and the German Federal Constitutional Court has recently refused to accept a constitutional complaint against the new implementation.<sup>3</sup> The UPC Agreement (hereinafter UPCA) has now reached the stage of provisional application. Germany is acting as a gatekeeper and will deposit its ratification once the preparations have been finalised.<sup>4</sup>

The end of the “long and winding road”, however, will also mark the beginning of new challenges. While the European patent jurisdictions agree on many principles, they have different traditions in detail. The first instance divisions and the Court of Appeal will have to find their own answers to many questions of substantive patent law, but also to formal issues such as the form and style of judgments or the framing of injunctions.<sup>5</sup> Given the relative homogeneity of patent law compared to general private law and given that national patent courts in Europe have long been in the habit of taking account of judgments from other European jurisdictions,<sup>6</sup> there is hope that the UPC will settle these differences in the long run. But some legal uncertainty in the first years of the Court’s existence is also inevitable.

This article will look into one aspect which has been controversial in several jurisdictions: can patent courts deny applications for injunctive relief, even if infringement is established, when an injunction would result in disproportionate hardships for the infringer or for third persons? Until recently, national answers to this question differed widely.<sup>7</sup> They ranged from the US approach, where the Supreme Court subjected injunctions to a flexible “four-factor test”, to the German approach, where injunctive relief was the automatic consequence of an infringement. In this article, I will argue that the UPC should steer a middle course. I will first try to show that there has been a trend towards convergence in the EU in recent years (II). Then I will look at the international and European framework and at the relevant UPC provisions which, in my view, establish that the UPC will have to

respect the principle of proportionality and refuse disproportionate injunctions, if only in exceptional cases (III). Even if the UPC will adopt this approach, it will still need to work out some details and decide, for example, if it can grant compensation in lieu of an injunction (IV). I will only discuss permanent injunctions, and I will, in particular, not enquire which effects the recent CJEU judgment in *Phoenix Contact v. Harting*<sup>8</sup> might have on future UPC decisions on the grant of interim injunctions.

This article is dedicated to Marianne Levin, the Grande Dame of Nordic intellectual property law. With her vast knowledge, her clear policy convictions, her power and her esprit she has shaped the law and inspired generations of students and academics. Since she has always advocated an IP protection which is adequate, but neither maximal nor overly broad, she may not entirely disagree with my thoughts on proportionality. I wish her good health and energy, and I hope that our longstanding co-operation will continue for many years to come.

## II FROM A CLASH OF CULTURES TOWARDS EUROPEAN CONVERGENCE

Traditionally and doctrinally, civil law and common law jurisdictions adopted diametrically opposite approaches to injunctive relief.

In Roman law, the *rei vindicatio* and the *actio negatoria* were the hallmarks of property.<sup>9</sup> By virtue of the former, the owner could require an unlawful possessor to hand over the object, and by virtue of the latter, he or she could demand the cessation of any interference. Following this tradition, courts in civil law jurisdictions have traditionally granted injunctions as a matter of course, without exercising any discretion and without requiring intent or negligence on the part of the defendant.<sup>10</sup> § 1004(1) of the German Civil Code, on which the provisions on injunctions in IP law were modelled, provides:

*“If the property is impaired in a way other than by deprivation or withholding of possession, the owner may demand the removal of the impairment from the interferer. If further impairments are to be expected, the owner may sue for injunctive relief.”*

In short: infringement + likelihood of further impairments = injunction. The duty not to infringe corresponds with the right to prohibit. An injunction is not a remedy which the court can grant if and when is appropriate, but the plaintiff has a legal right to an injunction in case of infringement.<sup>11</sup>

In common law legal systems, by contrast, injunctive relief is an *equitable remedy*, whereas there is a *legal* right to damages. Hence the courts have discretion, and they will not normally grant an injunction if damages provide adequate compensation. In the US, patent law had gone its own separate way for a while, as under the approach of the Court of Appeals for the Federal Circuit injunctions had usually been granted in cases of patent infringement. But the Supreme Court overruled this practice in its famous judgment in *eBay v. MercExchange*. The Court decided that injunctions in patent law were also subject to the principles of equity. Hence, they did not issue as a matter of course. Rather, the infringement court had to weigh four factors and require the plaintiff to demonstrate:

*“(1) that it has suffered an irreparable injury; (2) that remedies available at law are inadequate to compensate for that injury; (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.”<sup>12</sup>*

Since *eBay* it has become significantly more difficult for plaintiffs to obtain injunctions. In particular, nonpracticing entities (NPEs) find it difficult to apply for injunctions successfully.<sup>13</sup>

English law is also based on the dichotomy of common law and equity, injunctions are also equitable remedies, and the courts can grant damages in substitution of an injunction.<sup>14</sup> In several recent judgments, English courts have confirmed that injunctive relief can be withheld if it would lead to disproportionate results.<sup>15</sup> However, the courts do not conduct a four-factor analysis, but grant injunctions as a rule: “A general injunction to restrain future infringements is the normal remedy for the patentee.”<sup>16</sup> The burden on the party seeking to show that an injunction would be disproportionate has been characterised as “a heavy one”, at least when no other countervailing rights are in play.<sup>17</sup>

German law has recently moved from its formerly radical approach towards the more moderate English position. The “quasi-automatic” grant of injunctions<sup>18</sup> was increasingly criticised by some academic authors<sup>19</sup> but defended by others.<sup>20</sup> Over time, some industries also became concerned about the excessive effects of injunctions, par-

<sup>1</sup> In favour: Ansgar Ohly & Rudolf Streinz, ‘Can the UK stay in the UPC system after Brexit?’, GRUR Int. 2017, 1 = [2017] JIPLP 245; against: Carlo Luigi Ubertazzi, ‘Brexit and the EU Patent’, GRUR Int. 2017, 301.

<sup>2</sup> The first implementing act was declared unconstitutional by the German Constitutional Court: BVerfG, 30 February 2020, 2 BvR 739/17, GRUR 2020, 506.

<sup>3</sup> BVerfG, 13 July 2022, 2 BvR 2216/20 and 2217/20.

<sup>4</sup> UPC, press release of 27 September 2021, <https://www.unified-patent-court.org/news/germany-ratifies-protocol-provisional-application> (last visited on 6 September 2022).

<sup>5</sup> Whereas English courts generally order the defendants not to infringe the patent but allow defendants to apply for carve-outs concerning modifications, injunctions are usually adapted to the infringing embodiment in Germany. See, for England, *Illumina Inc v TDL Genetics Ltd*, [2019] EWHC 2405 (Pat) and Colin Birss et al. (eds.), *Terrell on the Law of Patents*, 19th ed., London: Sweet & Maxwell, 2022, para. 21-56, for Germany BGH, 10 May 2016, X ZR 114/13, GRUR 2016, 1031, para. 54 – *Wärmetauscher [Heat Exchanger]*.

<sup>6</sup> On this “harmonization by persuasiveness” see Jan Brinkhof & Ansgar Ohly, ‘Towards a Unified Patent Court in Europe’, in: Ansgar Ohly and Justine Pila (eds.), *The Europeanization of Intellectual Property Law*, Oxford: Oxford University Press, 2013, pp. 199, 203-207; Robin Jacob, ‘The Relationship between European and National Courts in Intellectual Property Law’, *ibid.*, pp. 185, 188-192.

<sup>7</sup> For an overview, see the country reports in Jorge L. Contreras and Martin Husovec

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<sup>8</sup> CJEU, C-44/21, *Phoenix Contact v. Harting*, on which see the critical note by Hermann Deichfuß, ‘Nochmals: Die Prüfung des Rechtsbestands des Patents im einstweiligen Rechtsschutz’, GRUR 2022, 800, who, remarkably, recommends the German courts not to follow this judgment as it is based on a wrong understanding of German patent law.

<sup>9</sup> See Frits Brandsma, ‘Actions in Roman and civil law for the protection of immovables’, in: Sonia Martin Santisteban and Peter Sparkes, *Protection of Immovables in European Legal Systems*, Cambridge: Cambridge University Press, 2015, pp. 9, 11, 19.

<sup>10</sup> While German law is used as an example throughout this article, Dutch, French and Italian law largely follow the same approach, see the taxonomy by Jorge L. Contreras and Martin Husovec, ‘Issuing and Tailoring Patent Injunctions – A Cross-Jurisdictional Comparison and Synthesis’, in *Injunctions in Patent Law* (*supra*, note 7), pp. 315-316.

<sup>11</sup> See Franz Hofmann, ‘Der Unterlassungsanspruch als Rechtsbehelf’, Tübingen: Mohr Siebeck, 2017, pp. 83-84.

<sup>12</sup> *eBay v. MercExchange*, 547 U.S. 388, 396 (2006).

<sup>13</sup> Christopher B. Seaman, ‘Permanent Injunctions in Patent Litigation after *Ebay*: An Empirical Study’, 101 *Iowa Law Review* 1949, 1988 (2016); with further distinctions John R. Allison, Mark A. Lemley and David L. Schwartz, ‘How Often Do Non-Practicing Entities Win Patent Suits?’, 32 *Berkeley Technology Law Journal* 237, 267, 277-288 (2017).

<sup>14</sup> Sec. 50 Senior Courts Act 1981, Lionel Bently and Richard Arnold, ‘United Kingdom’, in:

*Injunctions in Patent Law* (*supra*, note 7), pp. 261, 271.

<sup>15</sup> *Ibid.*, at 272-275.

<sup>16</sup> *Evalve v. Edwards Lifesciences*, [2020] EWHC 513 (Pat) at para. 73 per Birss J.

<sup>17</sup> *HTC v. Nokia*, [2013] EWHC 3778 (Pat) at para. 32 per Arnold J.

<sup>18</sup> As it was termed by Martin Stierle, ‘Der quasi-automatische Unterlassungsanspruch im deutschen Patentrecht’, GRUR 2019, 873.

<sup>19</sup> See Stierle, *ibid.*, and Franz Hofmann, ‘Funktionswidriger Einsatz subjektiver Rechte’, GRUR 2020, 915; Ansgar Ohly, ‘“Patenttrolle” oder: Der patentrechtliche Unterlassungsanspruch unter Verhältnismäßigkeitsvorbehalt?’, GRUR Int. 2008, 787; Christian Osterrieth, ‘Technischer Fortschritt – eine Herausforderung für das Patentrecht?’, GRUR 2018, 985; Julia Schönbohm & Natalie Ackermann-Blome, ‘Products, Patents, Proportionality – How German Patent Law Responds to 21st Century Challenges’, GRUR Int. 2020, 578; Ralf Uhrich, ‘Entwaffnung der „Patenttrolle“’, ZGE 1 (2009) 39.

<sup>20</sup> See the GRUR’s Position Paper on the Ministry of Justice’s Discussion Paper of 16 March 2020 and the Ministry’s Draft of 29 September 2020, available at [www.grur.de](http://www.grur.de) (last visited on 6 September 2022), Uwe Fitzner and Michael Munsch, ‘Der patentrechtliche Unterlassungsanspruch – ein Teil einer Familie im deutschen Rechtssystem?’, Mitt. 2020, 250; Mary-Rose McGuire, ‘Stellungnahme zum 2. PatModG: Ergänzung des § 139 I PatG durch einen Verhältnismäßigkeitsvorbehalt?’, GRUR 2021, 175; Winfried Tilmann, ‘Zu einem Unverhältnismäßigkeitsverbot im Patentrecht’, Mitt. 2020, 245.



*ve right. In this case the injured party is to be granted adequate monetary compensation. The claim for damages under para (2) shall remain unaffected.”*

It remains to be seen to what extent this provision will be successfully invoked by defendants before German courts in practice. Also, an academic discussion has started about the doctrinal nature and the practical calculation of the compensation which the patent owner can claim according to § 139(1), forth sentence, if the claim is excluded.<sup>23</sup> But despite the limited experience with the new provision, it seems that English and German law have converged. It will have to be seen whether other continental European jurisdictions will follow this trend.

### III THE LEGAL FRAMEWORK OF UPC DECISIONS ON INJUNCTIVE RELIEF

The UPC must apply EU law in its entirety.<sup>24</sup> It is bound by EU primary law and by EU regulations and directives, in particular the IP Enforcement Directive (IPRED),<sup>25</sup> which, in turn, must be interpreted in the light of the TRIPS Agreement. Remedies for IP infringement are governed by the “three sisters” of EU enforcement law,<sup>26</sup> which are set out in Article 3(2) IPRED: remedies must be effective, proportionate and dissuasive. According to Article 11(1) IPRED, which mirrors Article 44 TRIPS,<sup>27</sup> the courts may grant injunctions in cases of infringement. Article 12 IPRED adds that the courts may grant pecuniary compensation in lieu of an injunction if the infringer acted unintentionally and without negligence, if an injunction would cause disproportionate harm and if pecuniary compensation appears necessary. Many of the UPC provisions on remedies mirror the IPRED. Like Article 11(1) IPRED, Article 63 UPCA provides that the Court may grant an injunction against the infringer aimed at prohibiting the continuation of the infringement. Whereas initially Rule 118.2 also copied Article 12 IPRED, this reference was later deleted.

The UPC will have to decide, first, if applications for injunctive relief may be denied in cases of disproportionality and, second, whether the IPRED even prohibits the grant of injunctions in cases of disproportionality.

The wordings of Article 63 UPCA and of Article 11(1) IPRED differ from civil law provisions under which the patent owner has a right to an injunction. They express that the UPC has the power to grant injunctions, but not that it must do so in every single case. On the contrary, both provisions are reminiscent of the discretion enjoyed by common law judges.<sup>28</sup> This understanding is in line with the prevailing interpretation of Article 44 TRIPS, according to which a judicial discretion to grant injunctions is in conformity with TRIPS, at least as long as the practical exercise of this discretion does not generally undermine the effectiveness of IP enforcement.<sup>29</sup> What is more, Article 3(2) allows the EU courts to deny a remedy if it would be disproportionate. A possible objection might be derived from Article 12 IPRED, which allows the award of compensation in lieu of an injunction only in a very specific and, indeed, rare case, namely in the case of

ticularly in the ICT sector, where products are complex and sometimes realise thousands of potentially patented inventions. In particular, the automobile and the telecommunications industry lobbied for a statutory exclusion of injunctions in the case of disproportionality. The German Federal Supreme Court reacted to this discussion in the *Heat Exchanger* case and considered it possible to grant a defendant a “use by” period if an immediate injunction would be grossly disproportionate.<sup>21</sup> But the Court made it clear that disproportionality was an extreme exception. The case, in which Daimler was the defendant, concerned a heat exchange mechanism built into seats of convertible cars, which kept the neck warm when driving. The courts in the first two instances had found against infringement, and Daimler continued producing cars in which the mechanism was used. When the Supreme Court found infringement, based on the doctrine of equivalents, Daimler applied for permission to sell off the cars which had already been produced and for which the buyers were waiting. Given that the infringing component was very limited, that the cars were ready for delivery and that the first two instances had dismissed the infringement action, there would have been a strong case for granting a “use by” period, but the Supreme Court denied the application.<sup>22</sup> The fact that the patent was about to expire and that Daimler had not shown any interest in negotiating a licence may have been important motives for this decision. So, for a while, in German law, the possibility of suspending injunctive relief existed in theory, but was never applied in practice.

Parliament reacted and modified the provision of the German Patent Act which allows the grant of injunctions in cases of infringement, by adding a disproportionality exclusion. § 139(1) Patent Act now provides:

*“A person who uses a patented invention in contravention of sections 9 to 13 may be sued by the infringer for an injunction if there is a risk of repetition. The claim shall also exist if an infringement is threatened for the first time. The claim is excluded to the extent that it results, under the specific circumstances of the individual case and having regard of the principles of good faith, in disproportionate hardship to the infringer or third persons, which is not justified by the exclusi-*

an infringement which is neither intentional nor negligent. It could be argued *e contrario* that injunctions are mandatory in all other situations. Article 12 IPRED is a puzzling provision. It was cut and pasted from the German Copyright Act,<sup>30</sup> where, in the German tradition addressed above, it allowed an extremely limited and practically irrelevant exception from the plaintiff’s right to an injunction. Interpreted in the light of the EU proportionality principle and in the light of EU fundamental rights, however, Article 12 IPRED is best seen as no more than an example of a case in which a court can withhold an injunction, not the only case in which it is entitled to do so.<sup>31</sup> Also, Article 12 IPRED was not implemented in the UPC or in the Rules. Hence it was not meant to have a limiting effect by the drafters of the UPC.<sup>32</sup>

Another question is whether Article 3(2) IPRED also requires the UPC to deny an injunction if it would lead to disproportionate results. It could be argued that the IPRED only sets a minimum standard, and that it hence allows a disproportionality exception, but does not make it mandatory. The German Supreme Court in *Heat Exchanger* seemed to lean towards this position. The opposite view, however, was taken by Arnold J, as he then was, in *HTC v. Nokia*:

*“I consider that Article 3(2) of the Enforcement Directive permits and requires the court to refuse to grant an injunction where it would be disproportionate to grant one even having regard to the requirements of efficacy and dissuasiveness.”<sup>33</sup>*

Indeed, the proportionality principle would largely be devoid of any effect if it only provided a minimum standard and not also a ceiling. The proportionality principle not only concerns the IP system in general, but must be observed in each individual case, as Recital 17 IPRED clarifies, and according to Recital 24 IPRED prohibitive

measures are only to be granted “depending on the particular case, and if justified by the circumstances”. What is more, the proportionality principle must be interpreted in the light of fundamental rights and freedoms. While the CJEU has never stated explicitly that Article 3(2) IPRED also sets a maximum standard, it held in a different context, namely with respect to the imposition of monitoring obligations on internet service providers:

*“a general monitoring obligation would be incompatible with Article 3 of Directive 2004/48, which states that the measures referred to by the directive must be fair and proportionate and must not be excessively costly.”<sup>34</sup>*

This consideration only makes sense if Article 3(2) IPRED is understood as prohibiting national courts from imposing disproportionate remedies. Since the UPC is bound by the proportionality principle, Article 63 UPCA must be interpreted in the light of the proportionality principle and to *permit* and *require* the UPC to refuse the grant of an injunction in the case of disproportionality.

Two questions remain. First, the UPC could either adopt a unitary approach or allow the local and regional divisions to follow their national traditions and apply different approaches. The latter possibility, however, would defy the unitary nature of the UPC and would result in forum shopping. The UPC will have to adopt one single approach to the criteria for granting injunctive relief. Secondly, the UPC will need to decide between the US “four-factor test” and the more careful English and German approaches, according to which injunctions are the rule and a refusal to grant an injunction the exception. So far, none of the EU member states has adopted a “four-factor test”. Also, Article 3(2) IPRED requires the courts to balance proportionality against effectiveness and dissuasiveness. Injunctions play a central role in the patent system, which creates incentives to invent, to disclose, to inno-

<sup>21</sup> BGH, 10 May 2016, X ZR 114/13, GRUR 2016, 1031, at paras. 40-50 – Wärmetauscher [Heat Exchanger].

<sup>22</sup> *Ibid.*, at paras. 51-54.

<sup>23</sup> See *infra* at IV 2.

<sup>24</sup> Article 20 UPCA.

<sup>25</sup> Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights, OJ L 195, 16 [corrected version].

<sup>26</sup> On which see Ansgar Ohly, ‘Three principles of European IP enforcement law: Effectiveness, proportionality, dissuasiveness’, in: Josef Drexler et al., *Technology and Competition, Contributions in Honour of Hanns-Ulrich*, Brussels: Larcier, 2009, p. 257.

<sup>27</sup> According to which “the judicial authorities shall have the authority to order a party to

desist from an infringement”.

<sup>28</sup> Matthias Leistner and Viola Pless, ‘European Union’, in *Injunctions in Patent Law (supra, note 7)*, pp. 26, 30; A. Ohly (*supra, note 26*), p. 264. Winfried Tilmann, in: Winfried Tilmann and Clemens Plassmann (eds.), *Unified Patent Protection in Europe*, Oxford: Oxford University Press 2018, Art. 63 paras. 29-34 argues that the UPC is not given any procedural discretion when deciding about the grant of injunctions, but concedes that a use-by period may be justified by the prohibition of abuse in Article 3(2) IPRED.

<sup>29</sup> See WTO Panel Report WT/DS79/R of 24 August 1998, *EC v. India*, para. 7.66: Graeme B. Dinwoodie and Rochelle C. Dreyfuss, ‘Injunctive Relief in Patent Law under TRIPS’, in *Injunctions in Patent Law (supra, note 7)*, 5, 8, 22-23.

<sup>30</sup> § 100 German Copyright Act. This provision

already existed in the initial version of the Copyright Act of 1965 (then § 101).

<sup>31</sup> See Martin Stierle, *Das nicht-praktizierte Patent*, Tübingen: Mohr Siebeck 2018, p. 310.

<sup>32</sup> On the similar situation in UK law before Brexit, see *HTC v. Nokia*, [2013] EWHC 3778 [Pat] at para. 21; but see W. Tilmann (*supra, note 28*), Art. 63 para. 39: Since Article 12 IPRED was not implemented, the UPC may not even deny injunctive relief in the case set out in that provision.

<sup>33</sup> *HTC v. Nokia*, [2013] EWHC 3778 [Pat] at para. 32; see also Richard Arnold, ‘Injunctions in European Law – Judicial Reflections’, in: *Injunctions in Patent Law (supra, note 7)*, pp. 65-69.

<sup>34</sup> CJEU, C-324/09, *L’Oréal v eBay*, ECLI:EU:C:2011:474, at para. 139.

vate and to licence<sup>35</sup> by putting the patent owner in the position to keep third parties from using the invention. This mechanism is central, and it should only be dislodged in exceptional cases. Hence Article 3(2) IPRED, the common European tradition and economic considerations militate in favour of the moderate approach: injunctions should issue as a rule in patent infringements, their grant should only be denied in exceptional cases. As a sidenote, it is bitterly ironic that probably the English approach to the grant of injunctions will prevail in the UPC at a time when the UK has withdrawn from the UPC system.

## IV OPEN QUESTIONS

If the UPC adopts the approach suggested in this article, it will still need to clarify some details of the disproportionality defence and its consequences.

### 1 When to deny applications for injunctions?

First and most obviously the Court will have to define criteria governing the decision of whether to deny an application for an injunction. The English case-law, the new German statute, and also the US *eBay* test and the cases applying it may provide some guidance. But unlike in the US, the UPC should – and will probably – not conduct a balancing exercise in every single case but will only consider withholding the injunction exceptional circumstances justify this decision. Of course, every defendant who must stop using the invention suffers a disadvantage, as he or she will often have to stop the production, redesign products and will lose sales. But these usual negative consequences which are, as the new German statute puts it, “justified by the exclusive right”, do not yet result in disproportionality. The defendant, who bears the onus of proof in this respect, will have to show exceptional circumstances of the case.

The scenario which has probably been discussed most widely concerns complex products.<sup>36</sup> Particularly in the ICT sector, products such as mobile phones, but also increasingly cars and household appliances, embody large numbers of patented or at least patentable inventions. “Patent thickets” in this area make a freedom-to-operate analysis difficult, even for diligent producers. If only one component of a complex product infringes and if this component cannot easily be removed, the consequences of stopping the entire product from entering the market may have disproportionate consequences.

One of the four US factors is whether damages are an adequate remedy to compensate the plaintiff. The UPC will also have to take this criterion into account. However, it is just one of several criteria, and it should not be applied in isolation. This is particularly true with respect to non-practicing entities (NPEs), which find it difficult in the US under the *eBay* test to obtain injunctions.<sup>37</sup> The European approach will probably be more moderate. Not every NPE or patent-assertion entity (PAE) is a “patent troll” which abuses the patent system in order to extort undeserved profits.<sup>38</sup> On the contrary, they can significantly contribute to the efficiency of technology markets. Nevertheless, it is more likely that an NPE is adequately

compensated by damages than a producing entity which needs injunctive relief to defend its product market.

In this context, the Court can also take into account the conduct of the parties. If a PAE adopts a “snake in the grass” tactic<sup>39</sup> and waits unreasonably long before informing the defendant of the potential infringement, this will militate against an injunction. If, on the other hand, the defendant has not conducted a diligent search or has ignored licence offers, the Court will be more inclined to grant injunctive relief.

Injunctions can affect the interests of third parties and the public interest. This is most obvious in the case of medicine. An injunction to stop the production and sale of a COVID vaccine, for example, could endanger many lives.<sup>40</sup> It is no coincidence that Moderna, in its recently commenced legal action against Pfizer and BioNTech in the US and in Germany, does not claim injunctive relief, but only damages.<sup>41</sup> Another example in point are the heart valves cases, which were litigated both in England and in Germany. The defendant had produced artificial heart valves which infringed the claimant’s patent. Doctors and clinics could switch to the claimant’s product, but they needed time to adjust. An immediate injunction could have led to a shortage of artificial heart valves and might have put patients’ lives in danger. In England, the High Court suspended the injunction for a period of one year, which was the estimated time which doctors and hospitals needed to become used to the claimant’s product.<sup>42</sup> The Düsseldorf District Court, however, granted the injunction and argued that the Patent Act provided for compulsory licensing, the conditions of which should not be bypassed through the backdoor of proportionality.<sup>43</sup> This view also found prominent support in the German legal literature,<sup>44</sup> but it did not prevail when the Patent Act was amended. § 139(1) of the Act now explicitly states that the interests of third parties can justify the denial of an injunction. This approach is convincing. Compulsory licences grant the applicant the full right to use the invention. Since they significantly interfere with the owner’s right, they are rarely granted in practice.<sup>45</sup> Disproportionality, on the other hand, does not provide a full defence. The defendant remains an infringer and can still be ordered to pay damages. Only injunctive relief is excluded, and it is usually not excluded for the entire patent term but only for a limited period, as the heart valves case shows. At the European level, there is another important consideration. While patent enforcement will become supranational once the UPC is in operation, compulsory licensing remains national, even though the Commission now considers introducing pan-European compulsory licences.<sup>46</sup> So, the possibility of the defendant to obtain compulsory licences in each relevant EU country is a theoretical rather than a practical one, and is, hence, at best a weak argument against considering third-party interests when deciding about injunctive relief.

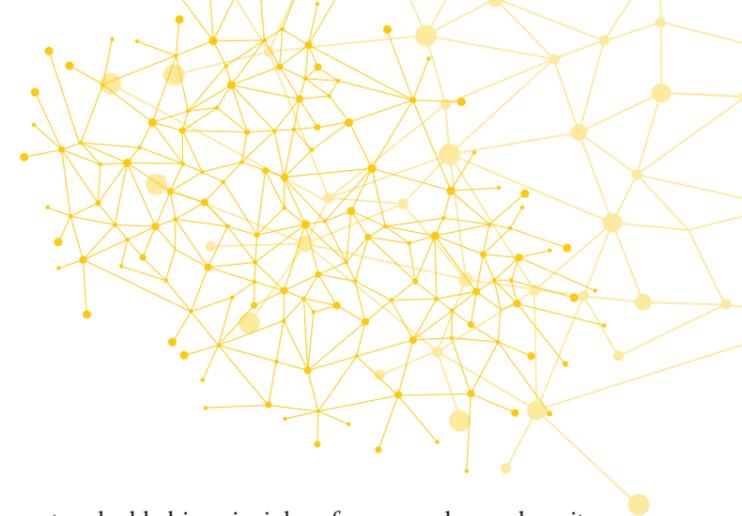
It should be stressed that the UPC, when deciding about the grant or denial of an injunction, should take all circumstances of the case into account and weigh all rele-

vant factors. It would be too wooden to state that “PAEs can never obtain an injunction”, that “patients’ interests always prevail” or that “an injunction should always be granted if the defendant rejected an offer for a licence”. Rather, the decision should be based on what the great Austrian legal theorist Walter Wilburg called a “flexible system” (“bewegliches System”): the strength of one factor can outweigh the weakness of another factor. The court is also flexible when deciding about whether to deny granting the injunction altogether or whether to suspend it for a limited period, for example for a “use by” or adjustment period.

### 2 Can the UPC grant compensation in lieu of an injunction?

The grant of an injunction may be disproportionate, but it does not follow that the defendant can use the invention for free. Under the principles of equity, common law courts can grant compensation in lieu of an injunction, both in general private law cases and in intellectual property law. This can also be done prospectively: US courts grant ongoing royalties when they have found infringement but have denied injunctive relief, but the principles of calculating the royalty are still in dispute. § 139(1) of the German Patent Act as amended in 2021 also explicitly provides that the court can grant compensation. So far, this provision has not been tested in any cases. As in the US, a controversial discussion about the legal nature of the compensation and about the principles of calculation has started.

Unlike German law, the UPCA does not explicitly empower the Court to grant compensation. As mentioned above, Article 12 IPRED, which provides for compensation in a very limited case, has not been implemented in the Rules.<sup>47</sup> And unlike US or English law, the UPCA is



not embedded in principles of common law and equity. Hence it is unclear if the UPCA can order compensation at all. The answer lies in the principle of proportionality itself. The grant of an injunction can be disproportionate, but it would be equally disproportionate to allow the defendant to use the invention for free. In the heart valves case,<sup>48</sup> for example, the High Court suspended the injunction for an adjustment period, but fairness requires that the defendant pay a reasonable licence fee for the time in which it is allowed to produce and sell the infringing product. Since an order of compensation is usually a necessary element of a proportionate solution, and since a compensation order is a minus compared to an injunction,<sup>49</sup> the principle of proportionality provides a sufficient legal basis. There would nevertheless be a case for including an explicit provision to this effect in a future amendment of the UPCA or of the rules. It should be added that the issue may not be as practically relevant as it seems at first sight. Even if the grant of an injunction is disproportionate, the infringement remains unlawful, and the patent owner retains his or her claim for damages in case of an intentional or negligent infringement under Article 68 UPCA.

<sup>35</sup> See M. Stierle (*supra*, note 31), p. 240.

<sup>36</sup> See Norman V. Siebrasse et al., ‘Injunctive Relief’, in: C. Bradford Biddle, Jorge L. Contreras, Brian J. Love & Norman V. Siebrasse (eds.), *Patent Remedies and Complex Products*, Cambridge University Press, 2019, pp. 115, 118-122; and the opinion of Justice Kennedy in *eBay v. MercExchange*, 547 U.S. 388, 397; *HTC v. Nokia*, [2013] EWHC 3778 (Pat) at para. 62 per Arnold J. (referring to the traditional analogy of a whistle on a battleship); Entwurf eines Zweiten Gesetzes zur Vereinfachung und Modernisierung des Patentrechts [Draft Second Act to Simplify and Modernise Patent Law], BT-Drucks. 19/15821, p. 54.

<sup>37</sup> *Supra*, note 13.

<sup>38</sup> On the extensive discussion on “patent trolls” see Mark A. Lemley & A. Douglas Melamed, ‘Missing the Forest for the Trolls’, 113 Colum. L. Rev. 2117 (2013); M. Stierle (*supra*, note 31) pp. 133-166.

<sup>39</sup> Term coined by Robert P. Merges & Jeffrey M. Kuhn, ‘An Estoppel Doctrine for Patented

Standards’, 97 California Law Review 1, 3 (2009).

<sup>40</sup> In the middle of the pandemic, the LG Düsseldorf granted an injunction concerning a patent on a flexible breathing tube despite the defendant’s argument that this was disproportionate in the light of the pandemic. One of the reasons advanced by the court was that at the time of the decision (June 2020) there were no indications that a second COVID wave was likely (!), LG Düsseldorf, 16 June 2020, 4c O 43/19, GRUR-RS 2020, 52267.

<sup>41</sup> See Jorge L. Contreras, ‘No Take-Backs: Moderna’s Attempt to Renege on its Vaccine Patent Pledge’, available at <https://blog.petrieflom.law.harvard.edu/2022/08/29/no-take-backs-modernas-attempt-to-renege-on-its-vaccine-patent-pledge/> (last visited on 6 September 2022).

<sup>42</sup> *Edwards Lifesciences v. Boston Scientific Scimed* [2018] EWHC 1256 (Pat), but see also *Evalve v. Edwards Lifesciences*, [2020] EWHC 513 (Pat).

<sup>43</sup> LG Düsseldorf, 9 March 2017, 4a O 28/16, GRUR-RS 2017, 104662 at II 1 a.

<sup>44</sup> Klaus Grabinski, ‘Injunctive Relief and Proportionality in Case of a Public Interest in the Use of a Patent’, GRUR 2021, 200, 202.

<sup>45</sup> In Germany, only two compulsory licences have been granted since 1945, of which only one was upheld by the Federal Supreme Court.

<sup>46</sup> The Commission has launched a public consultation on compulsory licensing, see the press release of 7 July 2022, available at [https://single-market-economy.ec.europa.eu/news/commission-seeks-views-and-input-compulsory-licensing-patents-2022-07-07\\_en](https://single-market-economy.ec.europa.eu/news/commission-seeks-views-and-input-compulsory-licensing-patents-2022-07-07_en) (last visited on 6 September 2022).

<sup>47</sup> See W. Tillman (*supra*, note 28) at para. 30, who concludes that the UPC does not have the power to award compensation in lieu of an injunction.

<sup>48</sup> *Supra*, note 42.

<sup>49</sup> M. Stierle (*supra*, note 31), p. 276.

If the UPC adopts the approach suggested here, it will also be able to grant compensation ex ante in the form of ongoing royalties. As in the US and in Germany, the calculation of the amount of compensation will be a challenge. In US law, the Federal Circuit in *Amado v. Microsoft*<sup>50</sup> rejected the argument that, once infringement was established, the defendant's continued conduct was intentional because the continued use was with the court's approval. On the other hand, according to the Federal Circuit the future royalty could not be equated with the damages assessed for the past.<sup>51</sup> A similar discussion has started in Germany under the new provision on compensation in § 139(1) of the Patents Act. Some authors argue that compensation should have a deterring or even a punitive effect.<sup>52</sup> Others do not go quite as far, but nevertheless think that the compensation should compensate the right owner for the loss of the threat potential of an injunction.<sup>53</sup> The third opinion compares the claim for compensation with provisions in the Civil Code which compensate owners for the entire or partial loss of rights and concludes that the action for compensation is, in essence, an action for unjust enrichment. Consequently, the amount of compensation should equal the value of the infringing use and should, hence, be calculated on the basis of a notional licence fee.<sup>54</sup>

It may seem premature to discuss this issue with respect to the UPC before the Court has even had the opportunity to decide whether claims for injunctions can be rejected on the ground of disproportionality at all. But one doctrinal and one pragmatic argument militate in favour of calculating compensation on the basis of a notional licence fee. The doctrinal argument is that a claim for damages requires intent or negligence whereas compensation does not require any subjective elements. Since the claim has less requirements, it should also go less far. The pragmatic argument is that it is almost impossible to determine the "threat value" of an injunction. The defendant's loss if the injunction is granted is not a valid proxy, because the injunction is disproportionate. But which amount is higher than a reasonable licence fee but lower than a disproportionately high licence fee? Rather than adding a standard "loss of injunction addendum", the courts should do what they can do best: determine a notional licence fee. The

UPC as well as national courts should resist introducing punitive damages through the backdoor of compensation.

### 3 Disproportionality and FRAND

The third question which will arise sooner or later is how proportionality relates to the FRAND principles in cases concerning standard-essential patents (SEPs). On the one hand, the enforcement of an SEP against an implementer who is willing to take a FRAND licence would be disproportionate, on the other hand the principles which emerge from the CJEU judgment in *Huawei v. ZTE*<sup>55</sup> and from national court decisions could be regarded as a *lex specialis*.

The UPC should and will probably look for an interpretation of the proportionality principle which is in line with the *Huawei* judgment. It should be noted that both proportionality and the notion of "abuse" in competition law are very general concepts which must be interpreted in the light of fundamental rights and freedoms. The framework for fair negotiations which the UPC outlined in *Huawei* equally provides guidelines for proportionality. Hence, an implementer who is offered a licence on FRAND terms will not be able to avoid its *Huawei* obligations by arguing disproportionality, unless there are additional circumstances of the case. But the principle of proportionality might become relevant in areas beyond the reach of the *Huawei* principles. First, it might provide a solution in cases of overdeclaration, i.e. in cases in which a patent owner has declared patents which later turn out not to be standard-essential after all. Article 102 TFEU does not apply, as the non-SEPs do not confer a dominant market position on the patent owner. But the patent owner's prior declaration could render the enforcement of the patent disproportionate. A second issue is succession in title. When a patent covered by a FRAND commitment is assigned to a third party, it is unclear if the assignee is bound by the FRAND declaration.<sup>56</sup> The principle of proportionality might provide the answer: If the assignee knows about the prior declaration and the implementer relies on it, a claim for an injunction is disproportionate, as long as the implementer fulfils its *Huawei* duties.

## V CONCLUSION

The UPC will be bound by the principle of proportionality (Article 3(2) IPRED), which applies not only to patent enforcement in general, but which must be observed in every single case. It follows that the UPC not only has the power, but even a duty to deny the grant of an injunction if it would lead to a disproportionate result. Unlike in the US under the "four-factor test" set out by the Supreme Court in *eBay v. MercExchange*, however, disproportionality will be an exception. It may apply, for example, in cases of complex products or when third-party interests, such as patients' interests, are at stake. If the UPC denies injunctive relief, proportionality will often require the Court to order a compensation payment. The UPC can do so, even without an explicit basis in the UPCA.

Continental patent lawyers should not be afraid of this flexibility. It will not undermine the effectiveness of the patent system. The principle of proportionality can be compared to a safety valve. It does not normally take the pressure off the kettle. But if the pressure becomes too high, the safety valve prevents the kettle from exploding. This is exactly what proportionality does.



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<sup>50</sup> *Amado v. Microsoft Corp.*, 517 F.3d 1353 (Fed. Cir. 2008).

<sup>51</sup> *Amado v. Microsoft Corp.*, 517 F.3d 1353 (1360) (Fed. Cir. 2008); see also *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312 (1342) (Fed. Cir. 2012).

<sup>52</sup> Fabian Hoffmann, 'Der Ausgleichsanspruch im Patentrecht', GRUR 2022, 286.

<sup>53</sup> Gerhard Wagner, 'Die Aufopferung des patentrechtlichen Unterlassungsanspruchs', GRUR 2022, 294.

<sup>54</sup> Ansgar Ohly, 'Der Ausgleichsanspruch gemäß § 139 I 4 PatG als Rechtsfortwir-

kungsanspruch', GRUR 2022, 303.

<sup>55</sup> CJEU, C-170/13, *Huawei Technologies v. ZTE*, ECLI:EU:C:2015:477.

<sup>56</sup> Several doctrinal possibilities for achieving this result have been suggested, for example a standard estoppel, see R.P. Merges & J.M. Kuhn (*supra*, note 39), an accessory character of the FRAND commitment, comparable to a mortgage in property law, see OLG Düsseldorf, 22 March 2019, 2 U 31/16 – *Improving Handovers*; but see the criticism of this approach by Lea Tochtermann, 'Das Schicksal der ETSI FRAND-Er-

klärung bei Übertragung des SEP', GRUR 2020, 905, 912-913; Tim Dornis, 'Standardessenzielles Patent, FRAND-Bindung und Rechtsübergang', GRUR 2020, 690, 692-696, or a solution on the basis of antitrust law principles, see M Leistner & Lukas Kleeberger, 'Die Drittwirkung von FRAND-Erklärungen aus kartellrechtlicher und vertragsrechtlicher Sicht', GRUR 2020, 1241, 1243-1247.





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