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LAW REVIEW

2021
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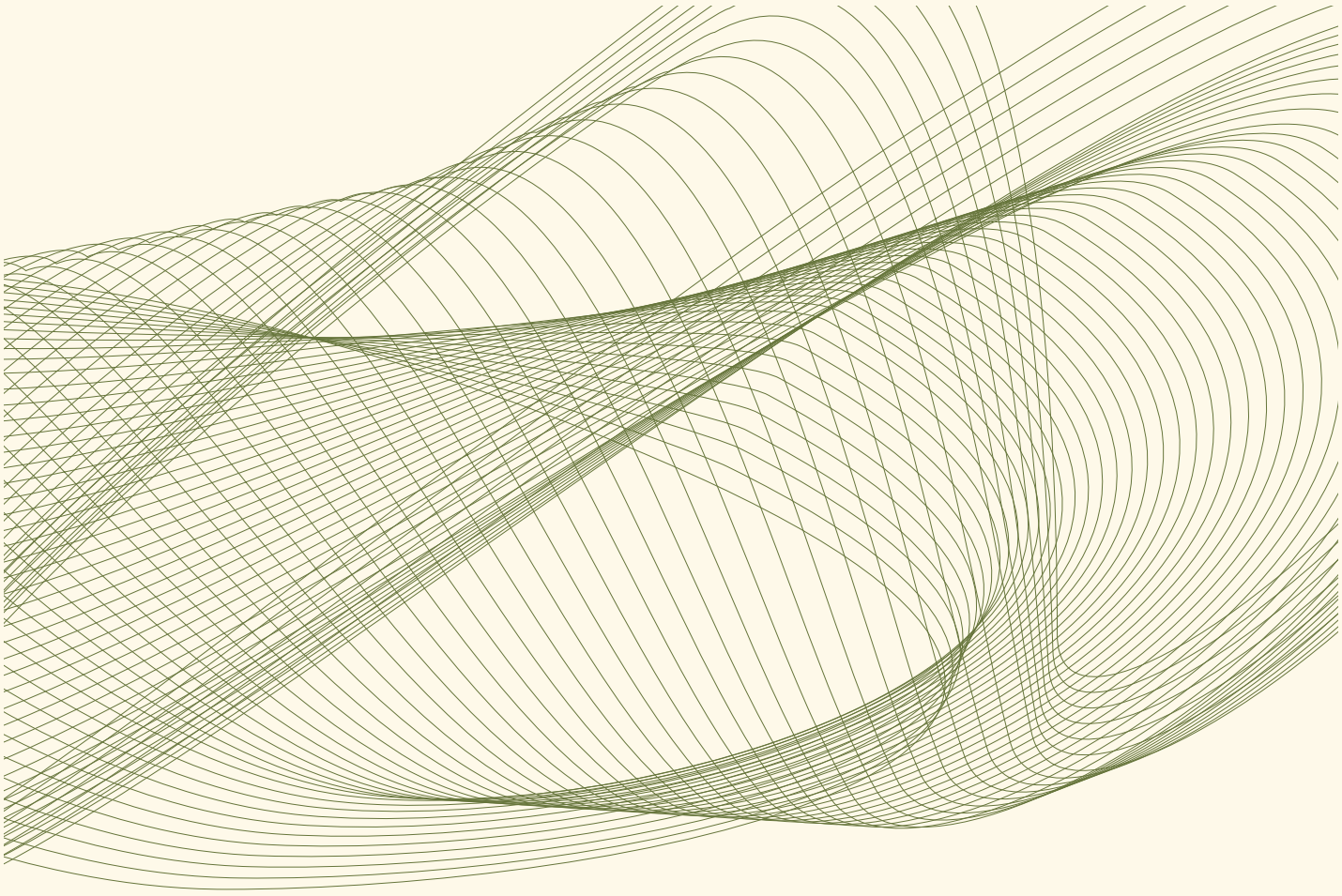

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Intellectual Property
LAW REVIEW

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Editorial

More than a year has passed since COVID-19 came into our lives, or to be blunt, took over our lives. We are affected by this unpredictable virus on a global scale, but the disruption is on a personal level; the loss of loved ones, or living with post-COVID conditions.

For many of us this year was a year of revelations. A year where we realized that the big great world could suddenly become so small. A year where we went from being able to travel to the other side of the globe, just because we wanted to, to a situation where we were confined to the limits of our own town. Changes of plans, cancelling of various forms of festivities and an uncertainty about what the future may bring the day after has dominated everyday life.

It has also meant working from home through Zoom or Teams, and experiencing a completely different working environment that in a peculiar way includes our colleagues' living rooms, pets and family members. At times, it has felt and still feels like living inside a big apocalyptic experiment.

Reflecting back to this year and what it brought, with the hope if not the certainty that we are heading towards normality makes us wonder what we keep from this experience. Apart from constantly washing our hands, of course!
It seems as we will keep that not all meetings need to be "irl", some of the travelling could be replaced by digital alternatives. But we will above all keep how important these "irl" meetings are, to exchange ideas and debate opinions, to create and brainstorm. How much we miss chatting in the corridors during breaks, the social events at conferences, the warm handshakes and the feeling that you are in a room full of people.

Networking and the need to be part of a context, in which you participate, give and take and as a team produce something new, has been decisive during this year. And although it required more and other efforts, since the natural meeting places, meetings, conferences and coffee breaks were lost, the will to work together, to find new forms of cooperation was obvious. This is also the story of this issue of Stockholm IP Law Review, dedicated to plant intellectual property protection. It is the story of our amazing student editors in chief, Alex Miura and Riana Harvey, who have actually never met "irl", who have worked closely with us, and with our great student editors, Pia Leonarda Riemenschneider, Anne Boender and Valentine Labaume, all situated in different parts of the world. And it is the story of the authors, who replied to our call for papers and contributed with their knowledge in topical articles. Some of these persons are old friends, others new acquaintances with which we are looking forward to a continued cooperation. You have all made this issue possible.

The contacts with the Community Plant Variety Office (CPVO) and its President Martin Ekvad, initially focusing on the contribution to Stockholm IP Law Review, has grown considerably to a formal co-operation agreement according to which students at the Master of Laws (LL.M) programme in European Intellectual Property Law at the Stockholm University Department of Law will be given the possibility to apply for internship at the CPVO, as well as the CPVO will be actively involved in the activities of the Master Programme. It has further led us to yet a new partner, CIOPORA (the International Association of Breeders of Asexually Reproduced Horticultural Plants). Even this co-operation has proven to be multilayered, through which CIOPORA will be involved in the activities of the Master Programme, and where students of the Programme will be able to follow the CIOPORA course modules for a reduced fee.

The articles of this issue concern different aspects of protection and exploitation of plant innovation. Martin Ekvad gives an overview of the CPVO and its setting in the legal system of EU plant variety protection. He also shares further insights into the work of the CPVO and personal reflections on plant innovation in the interview of this issue. Further, Edgar Krieger describes the UPOV legal system, the fundamental international convention in the field of plant protection. In her article, Pia Leonarda Riemenschneider analyzes the well-known Pepper case against the background of legal conflicts regarding the patent protection of biological breeding, methods, resulting from the amendment of Rule 28(2) of the European Patent Convention's Implementing Regulations. Roberto Manno discusses developments in CJEU case-law related to the increasingly important field of Plant Variety Rights, while Marco Baldassarra and Sabino Sernia analyze the impact of shrink-wrap licenses and exhaustion in the same field. Finally, Isabella Katz Migliori brings up the international perspective by providing for a discussion on plant-related IP rights in Brazil.

Finally, it seems only natural that an issue published under a pandemic would have a public health and pharma perspective. Iyad Al Khatib discusses points of collision between patent rights and the right to public health at times of pandemics, while Åsa Hellstadius and Håkan Borgenhäll discuss recent case-law from the The Swedish Patent and Market Court of Appeal concerning the possibility of destruction of patent protected products lawfully manufactured outside Sweden.

Next issue of the Stockholm IP Law Review will come in December 2021, in what we hope to be a post-pandemic time.

Åsa Hellstadius & Frantzeska Papadopoulou

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Interview with Martin Ekvad, president of the Community Plant Variety Office (CPVO)

By Riana Harvey, Alexandre Miura, Pia Leonarda Riemenschneider

ABSTRACT

Martin Ekvad is President of the Community Plant Variety Office (CPVO) since 2011. Prior to his elevation to the position of President, he held the position of Head of the CPVO Legal Unit from 2003. From 1996 to 2003 Mr. Ekvad worked as a lawyer (Advokat, Member of the Swedish Bar Association) in the law firm Linklaters, in Brussels and in the law firm Magnusson Wahlin Advokatbyrå, in Stockholm. Our Editors had the pleasure of talking with him and getting his opinion on a broad range of topics, from recent case law developments, the current state of Plant Variety Rights (PVR) in the EU, a discussion on the challenges in the registrability of PVRs, and also advice for young practitioners.

CAREER

SIPLR: We have seen that you have a background in private practice before you started your career at the CPVO. What are the biggest differences you have noted between working in a private practice and working for an EU institution? Are there any similarities?

Martin Ekvad: What I liked about practicing law at a law firm was the interaction with clients. Clients came with a legal problem related to their business and my job was to come up with solutions that fit their strategies. On the other hand, when working as a lawyer for an EU institution, it is important to be objective in your positions and decisions, always bearing in mind the interest of all parties to proceedings as well as those of third parties and the public. In fact, it resembles the work I did at the beginning of my career, when I worked for a Swedish court and prepared decisions and judgments for the judges.

The biggest difference is that when I worked with clients I had to make the interest of the client a priority. Another interesting part of working at a law firm was that I worked with many clients from a wide range of sectors. For instance, one day I could be working with a client in the pharmaceutical sector and the next day with a client in the banking sector. It was necessary – and very interesting – to learn about the business behind the legal issues and apply the legislation relevant to the circumstances at hand. Working at a law firm was also stimulating, since I could learn from more experienced lawyers. Working with a team of motivated professionals sharing the same aims was very rewarding.

When I started at the CPVO, I was concerned that the work would be surrounded by a certain monotony, as the CPVO deals only with plant variety rights. However, I soon learned that it is a complex area in which you need to have a good understanding of the breeding techniques used and that each species must be treated differently. In addition, techniques change and it is important to keep abreast of what is new. As a lawyer, I have also defended decisions before the Board of Appeal, the General Court and the Court of Justice of the EU. Thus, it is very stimulating to work as a lawyer at the CPVO.

SIPLR: Your career at the CPVO is impressive, starting at the legal department and moving up to your current position as President. What would you say are the biggest differences in responsibilities you have found between being Head of Legal and being President of the CPVO, and the biggest challenges in both positions?

Martin: When I worked as a lawyer, I advised and expressed my opinion to the President on legal matters relating to plant variety protection (PVP) matters, as well as institutional issues such as public procurement, staff regulations, access to documents and data protection. As President, I am ultimately responsible for everything that the CPVO is involved with. If things go well, I get the credit, even if my colleagues did the work, and if problems arise, I am responsible, even if a colleague made a mistake. The challenge of being President lies in trying to ensure that the objectives in the long and short term can be achieved with the resources available. Motivating staff is also an important part of the job. This is a challenge, at the same time as it is very rewarding.

I must admit that going from being a lawyer to being President was a bit tricky. There was a certain transition period before I got fully comfortable with a purely managerial position, leaving the legal work to others. It was a challenge to focus entirely on planning the work, motivating people (not just a small group, but the whole office), implementing strategies and structures and working with budgetary matters. Another very concrete example of the change was that as President, you always represent the Office. It is expected of the President to make presentations and speeches at meetings. Sitting in as a participant in a seminar has become very rare for me.

SIPLR: Compared with other IP rights, plant varieties are still unexplored. In your view, what were the needs of the stakeholders and the particularities of the subject-matter that resulted in the creation of a sui generis system for the protection of plant varieties? Why was there a need for a sui generis system, and do you think in retrospect that traditional IPRs would have been more appropriate? Do you think there might be a need for a revision of the current legal framework, and if so in which direction?

Martin: I would not say that the PVP system is unexplored. The output of the breeding industry is certainly quantitatively smaller than, for instance, the number of new trade marks, but for good reasons. It takes many years to breed a new variety – 20 years for many species. There is a limit to the number of varieties that can be created each year which have a commercial interest. If one looks at the number of new varieties created, the proportion of those varieties that is protected is quite high. That being said, it is still important to promote the PVP system, especially to SMEs.

The sui generis system that was set up for PVP is different from other IP rights. There will always be some controversy when one talks about IP protection of living material. This can be related to religious or ethical convictions, but also more pragmatic considerations, such as whether it is appropriate to give an exclusive right for food. The breeders' exemption allows all breeders to have access to germplasm, even from protected varieties. In fact, plant breeders rely on getting access to diverse plant materials in order to create new varieties. Ever since I started at the CPVO, some stakeholders in the breeders' community have been stating the protection provided is too weak and that the breeders' exemption should be taken away or at least be limited in time. It is considered unfair that once a well-performing variety has been created, competitors can immediately have access to it. I can certainly understand the arguments and have sympathy for such concerns, but all in all, the system fulfils its purposes. Breeding is constantly evolving and with new techniques such as CRISPR CAS there is the prospect of creating new varieties faster and more efficiently, with qualities that do not yet exist. This may trigger amendments in PVP and patent laws, but we are not yet there.

After the Second World War, it was essential to secure food supply. It was important to ensure that agriculture became efficient and one main element of this was to ensure that the seeds used were of high quality. At that time, public institutions were involved in breeding in many European countries. Private companies had to fund their activities differently, but the patent system was not adapted for plant varieties. Thus, there was a need for an IP system tailored to the specificities of the industry. Some European countries adopted IP protection for plant varieties. The UPOV Convention was adopted in 1961 and amended in 1978 and 1991.

In view of the concerns raised against monopolies for food, and other arguments I mentioned earlier, the breeders' exemption was introduced. This allows the use of protected varieties for the creation of new varieties and ensures that breeders have access to genetic material. An agriculture exemption has also been developed allowing farmers, under certain conditions, to reuse seeds on their own farms for certain species, without the authorisation of the holder of the plant variety right. Therefore, I think it was appropriate to create a sui generis system and I think it still functions well. However, as with any system, it must over time be adjusted to new technologies, as well as commercial and public interests,

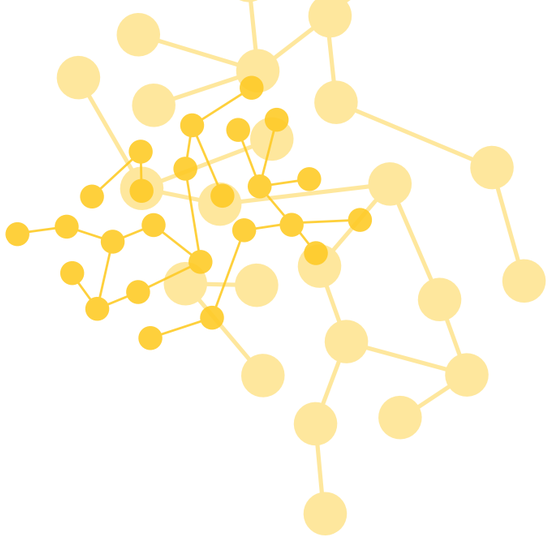
THE PROCESS OF REGISTRATION

SIPLR: In regard to the process of registration, it is known that the basic requirements for granting a CPVR (Community Plant Variety Right) are the DUS criteria (Distinctiveness, Uniformity, Stability), novelty and the variety denomination. Which requirements are the most difficult to assess and the ones most often challenged in application submissions?

Martin: During the technical examination, it is necessary to take into account all species of common knowledge (Article 7 of Regulation 2100/94/EC) for the purpose of assessing distinctiveness. This requires that examination offices have excellent knowledge of existing varieties.

Examination offices can either keep a living reference collection (i.e., plants are planted and kept in the field or indoors) or have documentation. Living reference collections are often kept for species such as trees, while seeds can be stored in seed banks. For many ornamental species, there is no living variety collection, so databases with photographs and descriptions are used to compare the variety being applied for with all the other varieties in the database. Thus, testing can be quite labour-intensive, especially in the agricultural field, where more than 100 reference varieties need to be grown in a given year.

Quantitatively, testing the D criterion is rather complex and cumbersome. In addition, for some species, the differences are rather small and must be determined using specific techniques. Overall, I would say that the D criterion is what keeps us most busy. If one looks at the decisions challenged, distinctiveness is quite often questioned, but issues relating to fees are more frequent.



SIPLR: How can there be so many decisions about the fees? Don't people know the fees in advance?

Martin: With fees, it is normally a question of whether the fees were paid in time. There can be misunderstandings as regards deadlines, but there can also be human errors on the side of the applicant, a bank or even the CPVO.

SIPLR: Next, we want to talk about the relationship with other offices and the nature of that relationship. Since the CPVO is entitled to delegate the technical examinations of certain aspects to component offices or offices in Member States, how does this relationship work?

Martin: When the office was created, existing systems were in place in many of the Member States, and that is still the case. Only Greece, Luxembourg, Malta and Cyprus don't have national protection systems. In addition, in order to market seeds in the European Union, you have to have a market authorisation issued by a national competent office. Once one of the national offices in the EU has granted an authorisation, the seeds can be sold throughout the European Union. This means that there are facilities in the EU Member States that are testing varieties. In the Basic Regulation (2100/94/EC), the legislator set out that the CPVO could either create its own facilities or use the already existing ones. The choice was rather easy. Why create new facilities and duplicate the work that is already in place? We only use examination offices in Member States that fulfil certain quality requirements, as determined by the Administrative Council based on a recommendation of the CPVO Quality Audit Service.

Some examination offices are entrusted with more than hundred species, while others test a very limited number of species. The CPVO enters into a Designation Agreement (Article 15 of Regulation 879/2009/EC) with an examination office, under which the examination office undertakes to perform tests and the CPVO undertakes to pay for the service carried out. For a very limited number of species, the CPVO relies on tests carried out by competent authorities outside the EU.

PLANT VARIETIES AND CASE LAW

SIPLR: In May 2020, the Enlarged Board of Appeal (EBA) made a decision in the Pepper case, a follow-up case to the Tomato and Broccoli cases, and held that products obtained from essentially biological processes are no longer patentable, as they fall under the patent exemption in Art. 53 (b) European Patent Convention (EPC). How does this decision impact the PVP system? What would have been the effects if the EBA had decided differently and those products could be patent-protected under the EPC?

Martin: Well, first of all, the processing of applications at the CPVO was not affected at all, because we don't assess patentability. The cases you refer to must be assessed under the EPC and not Regulation 2100/1994. Had the applications you refer to been granted a patent, meaning that products from essentially biological processes would be patentable, certain concerns would have been raised. There was the fear from some breeders and civil societies and many Member States that it would then be possible – through patents – to block the occurrence of natural characteristics and characteristics in varieties created through traditional breeding.

SIPLR: Indeed, in our understanding, this decision was very positive for the plant variety protection system. We would think it would cause the numbers of applications to increase, because if you are a breeder and can protect your product under the patent system, that would give you a somewhat stronger right, as there isn't a breeders' exemption, at least under the EPC. Thus, it might have at least a slight effect on the plant varieties system.

Martin: If the patent applications had been granted, one consequence could have been that the number of PVP applications would decrease. It might have been the case that some breeders would take the position that patent protection would suffice and that there would be no need to file PVP applications. However, this is not certain. The subject-matter of a patent differs from that of a plant variety and it is quite possible that breeders would file for both a patent and PVP, to get complementary protection. It is difficult to speculate on what the effects would have been and what the reaction of the industry would have been. Personally, I think that new breeding techniques should not be overregulated. It is important to take a science-based approach, not a fear-based one.

SIPLR: Article 14(3) of Regulation No. 2100/94/EC on Community plant variety rights (CPVR) incorporates a breeders' exemption. A limited breeders' exemption is also included in the Unitary Patent Law (Article 27(c) of the Agreement on the Unified Patent Court). Is there a difference between those two breeders' exemptions and do you think that the provision of the Unitary Patent Law will affect the plant variety rights protection in any way?

Martin: Yes, there is a difference – that's why it is referred to as a 'limited' breeders' exemption, which you will find in the patent legislation in some EU Member States, such as Germany, France and the Netherlands. The limited breeders' exemption means that you can use protected varieties in your research freely, without the authorisation of the holder, but you cannot market the resulting invention without the consent of the patent holder. Under the 'PVP breeders' exemption', as laid out in Article 14(3) of Regulation No. 2100/94/EC, you can use protected varieties to create a new variety and you can also market the new variety without the authorisation of the holder(s) of the varieties used in the breeding process. In the patent legislation, the research exemption is more limited. I do not see that there will be any particular effects on the plant variety rights protection (PVR) following the introduction of the Unitary Patent Law, since plant varieties cannot be protected by patents, and I believe that the PVR system will remain attractive for the purpose of protecting new plant varieties. However, I believe that it is to the benefit of society that the limited breeders' exemption was introduced in the Unitary Patent Law, since this will ensure access for breeders to genetic material.

SIPLR: As is set out under Article 13(2) and (3) CPVR, the cascade effect allows for PVR to extend to harvested material obtained through unauthorised use of the variant constituents of the protected variety, unless the right holder has had reasonable opportunity to exercise their right in relation to the variety constituents in question. However, the recent CJEU decision in *Club de Variedades Vegetales Protegidas v Adolfo Juan Martínez Sanchís* (C-176/18) involving Nadorcott clementines clarified that where there was an activity of planting a protected variety and harvesting the fruit thereof, which is not liable to be used as propagating material, authorisation of the right holder would be required so long as the conditions under Article 13(3) CPVR were met.

Martin: So, I think this case is a little bit complex because it mixes a lot of things. It relates to what a farmer and an applicant can do before a variety is protected – the provisional protection – and also the scope of protection of a harvested material.

The CJEU has affirmed that only plant materials with a capacity for propagation can fall under the primary protection regime enshrined in Article 13(2) of the Basic Regulation. This means that, in each case, what will need to be ascertained is whether or not the plant material in question falls under the definition of 'variety constituents', understood as 'entire plants or parts of plants as far as such parts are capable of producing entire plants'. So, it could indeed be defended that the CJEU has implicitly acknowledged that, where the product of a harvest itself constitutes propagating material, the activity of harvesting the concerned variety falls under Article 13(2) of the Basic Regulation, without triggering the application of Article 13(3) of the Basic Regulation. Otherwise, the qualification introduced by the CJEU, with the botanical distinction based on the reproductive nature of varieties used for ascertaining whether Article 13(3) of the Basic Regulation is applicable, would be rendered meaningless.

This assumption is also aligned with the underlying principle that the CJEU is seemingly seeking to ensure, namely, the principle that CPVR holders enforce their rights at the propagation stage of a variety. In any case, it will be interesting to see how the competent national courts of the EU Member States will apply the findings of the CJEU in practice.

What makes the issue complex is that plant material can sometimes be harvested material within the meaning of ordinary use of the language, but at the same time be a variety constituent within the meaning of the Basic Regulation. If a breeder sells potatoes of a protected variety as variety constituents to a farmer, the farmer will then plant them and subsequently harvest new potatoes. The farmer is allowed to sell the harvested potatoes for consumption (table potatoes). However, he cannot sell the harvested potatoes to someone in order for that person to reproduce them – that would be an infringement. Accordingly, if a potato is sold and eaten, it is legal, but if the same potato is used for multiplication purposes, it is illegal.

SIPLR: Further, the CJEU also stated that PVR holders are not entitled to prohibit performance of Article 13(2) of the Basic Regulation acts during the pre-grant protection period. Do you think that this could undermine the earlier point raised (in that farmers could be incentivised to use the pre-grant period to their advantage), and what would the implications – if any – be in practice?

Martin: I think the present situation can be improved. The provisional protection (i.e., the limited protection between when the application is published and when the title is granted by the CPVO) is rather weak. When you create a new variety, you want it to reach the market as soon as possible. Producers/farmers also want to have access to the best new varieties and, ultimately, so do consumers – so it is in everyone's interest that the varieties are being used. However, if the provisional protection available is weak, there is a risk that commercialisation is put on hold.

In the present situation it is not possible to enforce the plant variety right until the grant decision has been made and that it is clear that the plant variety is distinct, uniform, stable, and novel.

It is clear that the CJEU has marked a relevant distinction in scope between the provisional period of protection for a CPVR applied for (pursuant to Article 95 of the Basic Regulation), according to which only a right to claim reasonable compensation arises, and the definite period of protection afforded for a granted CPVR (pursuant to Article 94 of the Basic Regulation), according to which enforcement rights can be claimed by the CPVR holder from the time of the grant. This finding of the CJEU is not surprising, in so far as it stems naturally from the wording of the cited articles of Regulation 2100/94/EC. However, when considering the findings in this judgment as a whole, the practical impact for CPVR holders is significant, as overall they will lose a certain control over harvested material of their varieties. In essence, the door has been left ajar for farmers to propagate a given plant variety for

which a CPVR title has been applied but not yet granted, without being subject to liability for subsequent harvesting activities. However, once protected, CPVR holders can request reasonable compensation from those nurseries that multiplied their varieties during the provisional period of protection afforded to them.

Some practical implications arising from the described findings can indeed be anticipated. For instance, breeders may consider postponing the marketing of propagating material of the varieties for which the CPVR grant is pending, until the very moment when such CPVR title is granted. However, it should be borne in mind that the technical examination ('DUS' testing) of varieties for which CPVR protection has been applied can take up to several years depending on the species (e.g., fruit trees). Hence, breeders may be inclined to seek alternative solutions in the meantime and re-evaluate their marketing strategies. For example, they may consider entering into licensing contracts imposing certain restrictions on growers, where these contracts should of course be carefully and clearly drafted, so as to be valid and enforceable.

In the framework of the Commission's IP Strategy, it is foreseen that the Basic Regulation will be reviewed by the end of 2022. This provides a window of opportunity to address areas where protection can be improved, such as the provisional protection.

SIPLR: What is the rationale for the PVR not having a retroactive effect, like a patent?

Martin: I believe the rationale for the missing retroactive effect is that before it is ascertained that a variety complies with the criteria of protection, it should not be possible to hinder others from using this specific variety.

The period of protection of a CPVR is counted from the date of granting. Due to the examination process of the variety, quite some time may pass between the time of application and the grant of the CPVR, depending on the species of the variety and the duration of the DUS examination. Particularly for fruit varieties, the DUS examination takes a long time, often 3–5 years.

However, it is to the benefit of the propagators and growers, as well as consumers, to access new varieties as soon as possible. If there were no protection during this period, breeders would be reluctant to put varieties on the market. Under the current legal framework (Article 95 of the Basic Regulation), the breeder cannot act against unauthorised use of their variety during the period between the application and the grant of the CPVR. If there is an unauthorised use, the applicant has to wait until the right is granted before taking any action. After this, they may require reasonable compensation from any person who used the variety without their authorisation. The result of the current situation is that it is in some cases difficult for the breeder to control the volume and pace of the commercialisation of the variety applied for in the period between the application for plant variety protection and the grant of the title.

Since there is a public interest in using a new variety as soon as possible, it is reasonable that there is an incentive on the part of the applicant for placing the material of the applied-for variety on the market prior to the grant of protection, in order to put the breeder in a position to control the exploitation of their variety (i.e., to grant licenses and stop unauthorised production).

SIPLR: The previously mentioned case leads to questions concerning reasonable compensation. In particular, does a grower who has planted a plant variety during the pre-grant protection period have to pay a reasonable compensation to the PVR holder just once or does the reasonable compensation have to be paid on each harvest? Is there a threshold to what can be considered a reasonable compensation in this case?

Martin: No, there is not a fixed limit to the reasonability and whether the compensation has to be paid one, two, three or even more times. The amount would vary depending on the quantities used and the price for the species in question. If the provisional protection lasts for more than one year, it may be possible to collect a reasonable compensation for each year the variety is reproduced.

SIPLR: In the context of plant variety rights, it is possible to grant a compulsory license of rights of CPV protections under Article 29 of the Council Regulation (EC) No 2100/94 of 27 July 1994. In 2017, the first application for such a compulsory license was filed for a plant variety of blackcurrants ('Ben Starav'). The CPVO denied the grant of a compulsory license for several reasons. Would you say that the threshold for the grant of a compulsory license is quite high? Do you think that the instrument of a compulsory license will be used frequently in the future for plant variety rights, while it is provided as an option, and under what circumstances? If not, what would be the requirements, apart from public interest, to obtain a compulsory license?

Martin: I believe it is necessary to look at the purpose and reason for a provision, before it can be determined if the threshold is high or not. There are specific requirements in the legislation which have to be fulfilled for compulsory licenses to be granted. The PVP system was created as an incentive for breeders to provide varieties which are to the benefit of society. Compulsory licenses are important to ensure that the exclusivity granted is not misused. It is of particular interest for the legislator to ensure that when it comes to food supply, an intellectual property right should not prevail over public interest. However, when there are alternative varieties on the market, which are accessible to producers and consumers, there is in my view no pressing need to grant a compulsory license. This would undermine the protection and in the longer term the incentive to be innovative. I believe that the blackcurrant case did not set the threshold very high, in relation to the purpose for which it was created. Further, I do not see that the instrument of compulsory license will be frequently used since for most species, there are a number of interchangeable varieties available on the market.

CAREER OPTIONS

SIPLR: To conclude our interview, the last question is particularly interesting for students or young professionals who are interested in PVR. What career advice would you give to newcomers in the intellectual property field and also to those who are seeking a career in the public sector, especially at EU agencies?

Martin: When I studied law, I was attracted to the idea of working for an international organisation. I applied for a traineeship at the Commission and to some other international organisations – without success. In hindsight, I am very glad that I worked at a Swedish court, learning the details of litigation, as well as at law firms. This gave me detailed insights into dispute resolution. I believe that working with IP rights and working in the public sector can both be very interesting and challenging.

As a piece of career advice, I think that a traineeship/internship is a fantastic entryway to working with international organisations. For students or young professionals interested in plant varieties, such traineeships are provided by the CPVO. Further, the CPVO is also involved in the 'Pan-European Seal Professional Traineeship Programme', which is a common traineeship programme of the EUIPO and the EPO. Members of the Pan-European Seal are entitled to submit shortlists for both the EUIPO and the EPO, from which trainees are then selected. The CPVO is offering internship opportunities to trainees with an IP specialisation within the Pan-European Seal programme with the EPO and the EUIPO, and we also have people who have done a traineeship in one of the other IP offices. Internships/traineeships can be the first step towards a future position in the profession. For example, we have a lawyer who did a traineeship at the CPVO. After her traineeship ended, she first worked in other legal positions, but she later got a job at the CPVO in a competition. If you work as a trainee at a place like the EUIPO, the EPO or another international or national organisation and do a good job, it is probably more likely for these organisations to employ you in the future. If an employer has seen someone working well for six or twelve months, the risk of non-performance when this person is employed is reduced.

Otherwise, I think one has to be a bit persistent, seize the opportunities as they come and make the best of them. What is most important is having a positive approach to the work you are doing and trying to be passionate about it. This makes it much more likely that you will do a good job than if you are suffering while working. As the saying goes, when there is a strong wind, some hide behind walls to protect themselves, while others build a windmill.

SIPLR: Thank you for taking the time to speak with us and sharing your valuable knowledge, Martin Ekvad!

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Pia Riemenschneider is currently working as a trainee lawyer at DLA Piper in the field of patent law. After finishing the First State Examination in 2019 at the Rheinische Friedrich-Wilhelms-Universität (Bonn, Germany), she pursued her LL.M. in European Intellectual Property Law at Stockholm University in 2019/2020. In autumn 2021, Pia will start with her Second State Examination in Cologne, Germany.

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The CPVO and the EU-wide system of plant variety protection

By Martin Ekvad

ABSTRACT

The President of the Community Plant Variety Office (CPVO), Martin Ekvad, provides a short presentation of the background to the legal framework of the EU PVR system, the role of the CPVO and the future challenges and possibilities for the system as such.

THE CPVO AND THE EU-WIDE SYSTEM OF PLANT VARIETY PROTECTION

The Community Plant Variety Office (CPVO) turned 25 last year and one thing is sure: the creation of the EU plant variety right (PVR) system was a good decision for Europe. One application, one procedure, one technical examination and one decision for an EU-wide PVR valid in all EU Member States.

Over the past 25 years, the CPVO processed 72 000 applications and granted over 56 500 titles. Today, 29 000 new plant varieties are being protected by the CPVO. On average, more than 3 000 applications are processed each year and, about 20% of all applications come from applicants based in countries outside the European Union. In practice, the high number of new varieties means that EU farmers and producers get a better choice for their production.

HARMONIZATION AND COLLABORATION

As for every European success story, the advantages brought by the EU PVR system rely on harmonization and collaboration.

The CPVO has received applications for varieties belonging to more than 2 200 botanical taxa. More than 200 technical protocols have been drafted in cooperation with national experts and adopted by CPVO's Administrative Council. The protocols are mandatory for EU PVR, and for both national PVRs and listing purposes in EU Member States. This led to significant harmonization in variety testing and, as a consequence, it has increased transparency and improved legal certainty.

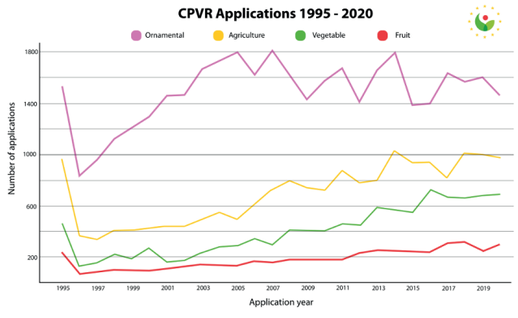
Digitalization has improved the quality of processing applications both for applicants and CPVO staff. Since 2010, applicants can file their applications online using CPVO's web platform called MyPVR. Over 27 000 online applications have been received and 98% of all applications are filed online today. In addition, MyPVR is now connected to the UPOV PRISMA system.

A UPOV-1991 SYSTEM AND THE DEVELOPMENT IN HORTICULTURE

The model of the UPOV-91 Act is very positive as it guarantees a fair return on investment to breeders, unleashing their innovative potential and encouraging investments in R&D for developing better performing varieties with less inputs and often with a better benefit-cost ratio. EU breeders can bring their new varieties to countries outside the EU that have signed the UPOV-91 Act, knowing that the level of protection in such jurisdictions complies with an adequate standard.

The high number of applications for horticultural varieties is a clear sign that a PVR system designed upon UPOV-91 is an important asset to the breeders' business model. In comparison to other crop sectors, ornamental breeders have made most use of the EU PVR system as applications for ornamental varieties represents nearly 54% of applications received since 1995. The number of applications in the fruit sector is increasing with a slow but steady pace.

Applications for ornamentals have been consistently high and in recent years the numbers have stabilized. There is probably a maximum number of new varieties that can exist in a competitive market and the number of applications cannot increase forever. In addition, experience shows that the ornamental sector is more sensitive to the overall market situation. Following the economic crisis and the austerity measures taken in 2008, the number of applications decreased whilst the situation for other crop sectors remained more stable. During 2020 there was also a decrease in applications and this may be connected to the pandemic although it is still too early to say.



On the other hand, applications in the fruit sector continue to increase which is a sign that there is a demand for new and better performing fruit varieties from the EU and the global market.

It can be noted that that there is fierce competition in the fruit sector and that there is a higher proportion of appeals and infringement procedures in that sector. In addition, there are particular challenges for testing fruits, especially apple mutants. Also, fruit breeders must ensure that the plant material they send for DUS (Distinctiveness, Uniformity, Stability) examination is virus-free, and breeders from third countries must be acquainted to the EU phytosanitary procedures before sending over plant material.

25 years of experience shows that cooperation with breeders' organisations, such as CIOPORA, has been instrumental and there is even more the CPVO would like to do to raise awareness about the strengths and challenges of the EU PVP system.

CHALLENGES AND OPPORTUNITIES OF THE FUTURE

Following a request by the CPVO Administrative Council, the Commission will this year propose that the term of protection for certain species, including flower bulbs, woody small fruits and woody ornamentals, will be prolonged from 25 to 30 years.

In the coming years, international outreach activities will intensify and the CPVO will establish an EU PVP Academy so that information on how plant variety rights are administered in the EU in accordance to UPOV-91 can become more accessible.

In a broader policy context, the CPVO follows closely all relevant policy initiatives of the European Commission, especially their new IP strategy released in November 2020 with a new focus on SMEs. We have also started analysing how the EU PVP system can contribute to more sustainable policies, and we are keen to have a good understanding of the market dynamics in our sector.

In this context, a sectorial study will be carried out by the European Observatory on Infringements of Intellectual Property Rights to assess the benefits of the EU PVP system on the EU economy, including at Member States and regional's levels. It will also look at how the EU PVP system can leverage sustainability in agriculture and horticulture in the context of the EU Green Deal and the UN Sustainable Development Goals. The study should be published by the end of 2021.

Even more important to us, the European Commission has indicated its intention to reevaluate the legislation governing the EU PVR system in 2022. This may be the perfect opportunity to reflect on any possible shortcoming and to propose targeted adjustment with the aim to meet the innovation, digital and environment challenges of the 21st century.

Martin Ekvad

Martin Ekvad is President of the Community Plant Variety Office (CPVO) since 2011. Prior to his elevation to the position of President, he held the position of Head of the CPVO Legal Unit from 2003. From 1996 to 2003 Mr. Ekvad worked as a lawyer (Advokat, Member of the Swedish Bar Association) in the law firm Linklaters, in Brussels and in the law firm Magnusson Wahlin Advokatbyrå, in Stockholm.

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Plant variety protection under the UPOV 1991 Act

Provisions, Loopholes and Possible Remedies

By Edgar Krieger

ABSTRACT

The UPOV 1991 Act is widely considered a key milestone in establishing a sui generis system of Plant Variety Protection across the world. In 2021, thirty years after its adoption, 60 countries have joined the 1991 version of the UPOV Convention by depositing their instruments of accession that fulfil the minimum of the 1991 Act's requirements. While progressive for its time, the UPOV 1991 framework may no longer accommodate the present-day developments of the global horticulture. Following the massive globalization of horticultural value chain, the UPOV system may benefit from a critical evaluation from the contemporary breeders' perspective that CIOPORA represents. This article will highlight the main provisions of the UPOV 1991 Act and pinpoint the loopholes that may have detrimental effects on protection of breeders' rights, hence jeopardizing the incentives for innovation.

On 19 March 1991, then 20 UPOV members adopted the third version of the International Convention for the Protection of New Varieties of Plants, the UPOV 1991 Act. For thirty years now, breeders - the ultimate users of the UPOV sui generis system of Plant Variety Protection (PVP) - have been testing the UPOV legal framework with sometimes sobering results. For once, in comparison to other systems of Intellectual Property rights, PVP still lacks clarity and well-established enforcement mechanisms that long exist in other IP protection frameworks. While discourse surrounding UPOV often drifts towards political debate, for CIOPORA, the International Community of Breeders of Asexually Reproduced Horticultural Plants representing breeders' interests in the area of IP protection since the foundation of UPOV in 1961, the focus has been and remains on the system's factual legal effectiveness in protecting incentivizing innovation. Thirty years after the adoption of the UPOV 1991 Act, let's examine what protection is offered by the system and whether it lives up to its promise.

PROTECTION FOR ALL GENERA AND SPECIES

Under the 1978 Act of UPOV, countries were required to provide protection to a minimum of 24 genera and species. The 1991 Act raised the bar to all genera and species within a period of five years for the existing UPOV members and within ten years for new members. While positive in its core, a PBR system cannot be considered "effective" in the meaning of Article 27 (3) (b) of the TRIPS Agreement as long as it does not provide protection to all genera and species.

WHAT IS PROTECTED?

The UPOV system was mainly created to accommodate the seed world. In a nutshell, the system of Plant Breeders Rights (PBR) is meant to protect the seed, but not the grain[1]. A tricky situation, as grain can be used both as seed and for processing in the food chain and animal feed. So, when is grain "food" and when is it "seed"?

Grain is definitely "seed" if it has been conditioned for "sowing" for propagation purposes, for instance, when pesticides and fertilizer have been applied. Pure, unconditioned grain is considered harvested material by most. Apples are harvested material, too, as they are meant for consumption and are not capable of producing apple trees of the same variety. However, most cut flowers, i.e. those with meristematic cells, are capable of producing entire plants true-to-type.

Although propagating material and harvested material are key terms of the UPOV system, they are not defined in the UPOV Acts. Consequently, definitions of propagating material vary greatly across UPOV members' laws.[2] For a while now, CIOPORA has been pleading for harmonization of the definitions worldwide.

Propagating material should include any reproductive or vegetative material of a plant from which, whether alone or in combination with other parts or products of that or another plant, another plant with the same characteristics can be produced. Additionally, it should be clarified that propagating material that has been harvested in a technical sense, is considered propagating material only . *Only material of a variety which is not capable by any means of producing another plant with the same characteristics should be deemed harvested material in the legal sense*. If not feasible from the socio-economic standpoint, a distinction should be made between agriculture and horticulture, so that the definition of the vegetative propagating material in horticulture could be broadened.

PROTECTION OF HARVESTED MATERIAL

After a long debate[4], the obligatory protection of harvested material has been included into the 1991 Act at the price of two conditions: (1) if the harvested material was obtained through the unauthorized use of propagating material of the protected variety, and (2) if the breeder hasn´t had reasonable opportunity to exercise his right in relation to the said propagating material.

The conditions were attached as UPOV members were not prepared to allow breeders to freely exercise their Intellectual Property rights over the grain instead of seed[5]. The result: a too narrow concept, particularly for asexually reproduced ornamentals and fruits. First, unauthorized acts can only occur in a territory where a breeder's right has been granted and is in force[6]. The burden of proof for the unauthorized use of propagating material lies with breeder, who can only exercise his right over harvested material if he had no reasonable opportunity to exercise the right in relation to the propagating material.

Due to globalization, ornamental and fruit varieties are increasingly grown in territories with no or low-level IP protection with harvest being exported to high-consumption countries. For instance, the export value of ornamentals from Ethiopia to the Netherlands has increased by the whooping 27,000%, whereas the export value of fruits from Argentina to the USA increased by 6,350% between 1995 and 2018[7]. Hence, it is high time for the UPOV members to re-consider these restrictions and provide breeders with the same freedoms as holders of Patents or Trademarks. As one of the world's most influential IP scholars Prof Dr Joseph Straus points out: "With the exception of the necessity to access protected/patented material no legal/economic justification exists to treat innovations/inventions and innovators/inventors of ornamentals and fruit trees any different than those in other areas of technology!"[8] If necessary, also here a distinction could be made between agricultural and horticultural crops.

Essentially Derived Varieties (EDV)

The basic purpose of the EDV principle in the 1991 Act of UPOV was to provide effective protection to a breeder who developed an original genotype from crossing and selection, by bringing mutants, GMO, and varieties developed by recurrent backcrossing into the scope of protection. Nowadays, New Breeding Technologies (NBT), such as CRISPR, enable multiple modifications of an Initial Variety in one act of derivation in a short period of time, and thus have the potential to undermine the protection of the Initial Variety, unless a sufficiently broad interpretation of the EDV principle is agreed upon among UPOV members. While the current UPOV Explanatory Notes (EXN) on EDV contains a very narrow interpretation, thanks to joint efforts of global breeder associations, the EXN is under review now. There is hope that the next EXN will reanimate the spirit of EDV principle by affirming that mono-parental varieties and varieties resulting from recurrent backcrossing are typically EDVs.

1 Barry Greengrass, "The 1991 Act of the UPOV Convention" in UPOV Publication No. 747(E), Seminar on the Nature of and Rationale for the Protection of Plant Varieties under the UPOV Convention, Pretoria, South Africa (UPOV 1996) 55.

2 The two main concepts are "intended for propagation" and "capable of producing entire plants true to type".

3 Case C-176/18 Club de Variedades Vegetales Protegidas v Adolfo Juan Martínez Sanchís [2019] ECLI:EU:C:2019:1131, Opinion of AG Øe.

4 The proposal to make the protection of harvested material optional was rejected by four votes for, 13 votes against and one abstention.

5 Greengrass (n 1) 55.

6 UPOV Explanatory Notes On Acts In Respect Of Harvested Material 2013, para 4. This narrow interpretation of "unauthorized use" was recently confirmed by the Court of Justice of the European Union: Case C-176/18 Club de Variedades Vegetales Protegidas v Adolfo Juan Martínez Sanchís [2019] ECLI:EU:C:2019:1131.

7 The Observatory of Economic Complexity. OEC. https://oec.world accessed in February 2021; Food and Agriculture Organization of the United Nations. FAOSTAT Statistical Database. http://www.fao.org/faostat/en/#data/QC accessed February 2021.

8 Prof. Dr. Joseph Straus, 'Patents for Plant-Related Inventions. The Current Legal Situation and Possible Solutions' (Venlo, the Netherlands, 2012).

DISTINCTNESS AND PREVENTION OF PLAGIARISM

Time and time again, the EDV principle is mentioned as a prevention tool against plagiarism. While preventing plagiarism is a noble goal, the EDV principle is not the right instrument to achieve it. Mutants, particularly those resulting from NBT, are not plagiaristic but innovative. So are the varieties resulting from genetic engineering or recurrent backcrossing and stacking[9].

The main plagiarism prevention tool, included in the UPOV 1991 Act, is the provision about "varieties, which are not clearly distinguishable from the protected variety", Article 14 (5) (a) (ii). Surprisingly, according to the records of the Diplomatic Conference 1991, this concept was not at all discussed and was only mentioned twice - both times by the first CIOPORA Secretary General René Royon[10].

The "not clearly distinguishable" varieties are slightly different from the pre-existing reference variety but are not different enough to be considered "clearly distinguishable". According to the law, for such varieties, no PBR protection shall be granted. Additionally, such varieties fall directly into the scope of protection of the protected variety, irrespective of whether they are derived from the protected variety or not. Unfortunately, this principle of "not clearly distinguishable" varieties is not commonly applied in UPOV's practice as DUS characteristics are not meant to be important in the sense of value but are used solely for making a botanical distinction[11]. Due to a very small minimum distance requirement, based on a purely botanical approach, even varieties with minor and trivial botanical differences from the reference variety often pass the distinctness test, with the unfortunate result that the scope of PBR protection covers only the protected variety itself and not the plagiaristic varieties. This is a unique situation in IP laws. Other IP systems include a tool to prevent plagiarism: the inventive step/non-obviousness-test and doctrine of equivalents test in Patent law, as well as the confusing similarity test in Trademark law.

A REMEDY FOR WEAKNESSES

The UPOV 1991 Act brought some remarkable improvements for breeders, at least on paper. However, in practice, the improvements often do not suffice, either because of not going far enough, like in the case of the limited protection of harvested material, or due to a too narrow interpretation, like in the case of EDV and Minimum Distance. A revision of the UPOV 1991 Act would provide an opportunity to remedy the existing weaknesses and to give breeders what they deserve – effective protection for their innovations.

About CIOPORA:

CIOPORA is the International Association of Breeders of Asexually Reproduced Horticultural Plants. Breeders of such varieties account for two-thirds of all Plant Variety Right (PVR) titles in the world. For 60 years, CIOPORA has been representing these breeders in all matters of Intellectual Property (IP) protection, aiming to foster an environment where innovation can flourish. The main priority of CIOPORA is the constant development and enhancement of systems of Intellectual Property protection for plant innovations. CIOPORA enjoys the observer status at the Administrative Council of CPVO and the International Union for the Protection of New Varieties of Plants (UPOV). CIOPORA unites breeders of all asexually reproduced horticultural plants with a broad portfolio of species and varieties on the market.

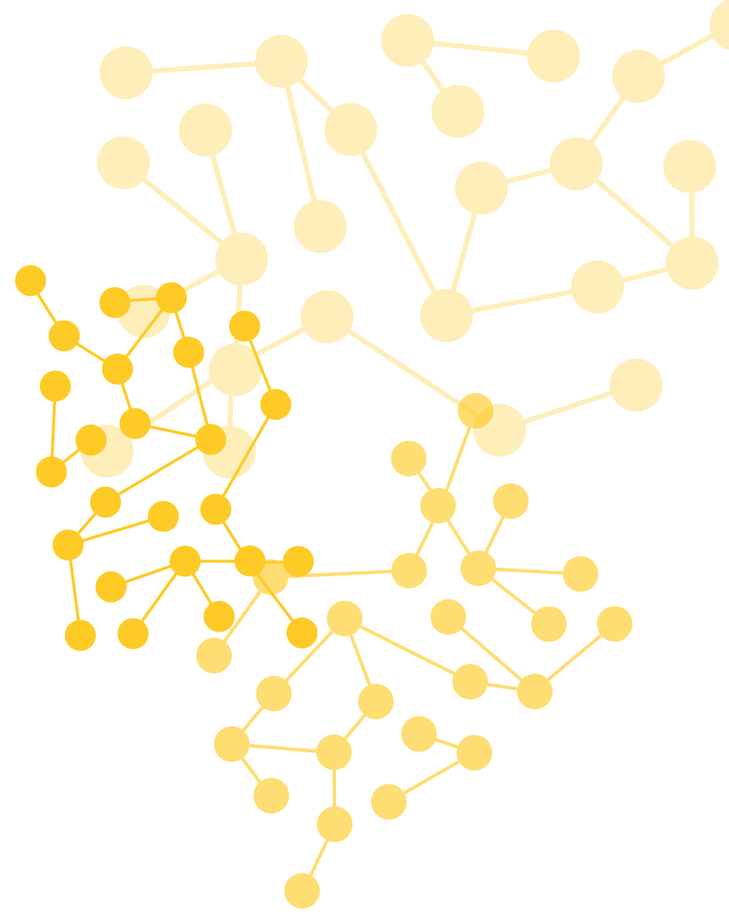
CIOPORA is a member-based, non-profit organization with currently 130 members from over 26 countries on five continents.

CIOPORA: Uniting Breeders, Protecting Innovation.
http://www.ciopora.org

[9] By way of stacking two or more traits of interest are combined into a single plant.

[10] UPOV, 'Records Of The Diplomatic Conference For The Revision Of The International Convention For The Protection Of New Varieties Of Plants', Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants (UPOV 1991) 340, 1060.1 and 1060.2.

[11] Greengrass (n 1) 56.



Edgar Krieger

CIOPORA Secretary General Dr Edgar Krieger has extensive experience in the field of Intellectual Property protection for plant innovations and has held the position of CIOPORA Secretary General since 2004. Prior to CIOPORA, Dr Krieger worked as a lawyer at an international law firm specializing in IP protection, particularly Plant Breeder's Rights, advising agricultural breeders in hundreds of court cases up to the European Court of Justice. Dr Krieger has a law degree from the University of Bonn and a degree in Business Administration from the Aachen University of Applied Sciences. He completed his doctoral dissertation on the topic "Farmers' Exemption in Germany" at the Philipps University of Marburg.

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Who owns the pepper?

An assessment of the conflicts resulting from the amendment of Rule 28 (2) of the European Patent Convention Implementing Regulations

By Pia Leonarda Riemenschneider

ABSTRACT

The present article focuses on the recent decision of the Enlarged Board of Appeal in the Pepper case. It examines the impact of the amendment of Rule 28 (2) of the EPC Implementing Regulations on the scope of the exclusion for essentially biological processes for the production of plants in Art. 53 (b) of the European Patent Convention EPC. It further contains an analysis of the internal hierarchy of the institutions within the European Patent Office and focuses in particular on the question, whether the Rules of the EPC Implementing Regulations take precedence over the decisions of the Enlarged Board of Appeal. Furthermore, an assessment of the provisions of the European Patent Convention and the general principles of law should shed light on the question, whether the Administrative Council was empowered to amend Rule 28 (2) of the EPC Implementing Regulations.

1. INTRODUCTION

Tomatoes, broccoli, pepper, melons – we encounter vegetables and fruits almost every day in the supermarkets, in restaurants and on our plates at home. But who owns the vegetables and fruits that we buy and consume?

This question has garnered more and more attention as modern genome editing techniques altering the genetics of plants have developed in recent years. The goal behind such manipulation of plant genetics is to discover new, beneficial properties increasing the effectiveness of lage-scale farming.[1] Biotechnology and seed companies have then looked for the most effective legal protection for their research investments and have therefore filed patent applications for new, genetically modified plants.[2] However, many non-governmental organizations and smaller plant breeders fear that patents on plants could endanger biodiversity and that only large seed companies would profit from them.[3] The central question in the field of patents on genetically modified plants is therefore which plants, parts of plants or products deriving from them should be permitted to protect through patents. This question has been discussed several times by the Technical Board of Appeal (TBA) and the Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) in the last couple of years, in relation to the exclusion for essentially biological processes for the production of plants set out in Art. 53 (b) of the European Patent Convention (EPC).[4], [5] This issue is now said to have been finally resolved.

On 14 May 2020, the EBA of the EPO published its long-awaited decision in case G 3/19,[6] known as the *Pepper* case. With this decision, the EBA resolved an almost ten-year conflict concerning the patentability of plants and plant material, to the effect that these will not be patentable in the future if they are obtained exclusively from essentially biological processes. The question of the interpretation of Art. 53 (b) of the EPC has thus been clarified, at least for the time being. However, this case with all its history has raised far more questions than solely those related to the issue of the patentability of products obtained from essentially biological processes. Indeed, it raised the question of the importance of a decision by the EBA and the power structure between the organs of the European Patent Organisation (EPOrg) and their relationships to the European Union (EU).

2. LEGAL DEVELOPMENT BEFORE THE PEPPER CASE

In order to analyze the decision of the EBA and the resolution of the aforementioned conflicts more closely, the initial situation before the referral must be examined.

Within the EU, the legal framework for the patentability of plants obtained through an essentially biological process is governed by a hybrid system. This means that the patentability is determined by two separate and unrelated legal systems, namely the Biotech Directive (BD),[7] an EU law, and the EPC, an intergovernmental treaty.[8] Not only the provisions of these legal sources, but also the interpretation of the Articles of the BD by the Court of Justice of the European Union (CJEU), determine the patentability of essentially biological processes and the plants obtained from them. Furthermore, the patentability of those processes and plants is also determined by the interpretation of the provisions of the EPC and the Rules of the EPC Implementing Regulations[9] by the Boards of Appeals (BoA) and the EBA of the EPO.[10] Until now, there has been no judgment from the CJEU concerning the exclusion of patentability for essentially biological processes for the production of plants or for the products obtained from such processes.

However, the EBA has already expressed its opinion on the interpretation of the exemption set out in Art. 53 (b) EPC several times.[11] In its latest decision in the *Pepper* case, the main question was whether products obtained from essentially biological processes were patentable. The EBA has already given its opinion once with regard to this question. In the consolidated cases *Tomatoes II*/*Broccoli II*, the EBA decided in March 2015 that the exclusion of essentially biological processes for the production of plants in Art. 53 (b) EPC did not impact on the admissibility of a product claim related to plants or plant material such as a fruit or plant parts.[12]

This ruling received a lot of criticism, not only from policymakers, but also from breeders' associations. Both saw the potential risk for breeders not remaining competitive because of limited access to biological material and the market concentration of large seed companies.[13]

The European Commission composed a statement for the interpretation of the BD in November 2016, in which it disagreed with the decision of the EBA made in *Tomatoes II/ Broccoli II*.[14] It clarified that the intention of the BD legislator was that products resulting from essentially biological processes should not be patentable.[15] As a result, the President of the EPO at the time, Benoît Battistelli, suspended all then-current proceedings concerning such matters.[16] The Administrative Council of the EPOrg considered the statement of the European Commission

1 Michael Edgerton, "Increasing Crop Productivity to Meet Global Needs for Feed, Food, and Fuel" [2009] 149 (1) Plant Physiology 7; Jean-Paul Chavas, Guanming Shi and Joseph Lauer, "The Effects of GM Technology on Maize Yield" [2014] 54 (4) Crop Science 1331, 1335.

2 Michael Kock, "Patents for Life: Toward an Ethical Use of Patents on Plant Innovations," in: Thomas Berg, Roman Cholij and Simon Ravenscroft, Patents on Life: Religious, Moral and Social Justice Aspects of Biotechnology and Intellectual Property (Cambridge University Press 2020) 227, 230.

3 This discussion is reflected in the amicus curiae briefs to the cases Broccoli II/Tomato II (G 2/12), see https://www.epo.org/law-practice/case-law-appeals/eba/number.html accessed 11 April 2021.

4 Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.

5 Decision of the EBA of 09 December 2010, Broccoli/PLANT BIOSCIENCE, G 2/07, ECLI:EP:BA:2010:G000207.20101209; Decision of the EBA of 09 December 2010, Tomatoes/STATE OF ISRAEL, G 1/08, ECLI:EP:BA:2010:G000108.20101209; Decision of the EBA of 25 March 2015, Syngenta Participations AG and another v Plant Bioscience Limited, G 2/12, ECLI:EP:BA:2015:G000212.20150325; Decision of the EBA of 25 March 2015, State of Israel - Ministry of Agriculture v Unilever N.V., G 2/13, ECLI:EP:-BA:2015:G000213.20150325.

6 Opinion of the EBA of 14 May 2020, Pepper (follow-up to Tomatoes II and Broccoli II), G 3/19, ECLI:EP:BA:2020:G000319.20200514.

7 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ 2 213/13.

8 Rob J Aerts, "A switch on a switch on a switch: the status of harmonisation of biotech patent law in Europe" [2019] 4 (9) European Intellectual Property Review 541.

9 Implementing Regulations to the Convention on the Grant of European Patents of 5 October 1973 as adopted by decision of the Administrative Council of the European Patent Organisation of 7 December 2006 and as last amended by decision of the Administrative Council of the European Patent Organisation of 15 December 2020 as in force as from 1 April 2021.

10 Aerts (n 8) 541.

11 See, e.g., G 2/07, Broccoli/PLANT BIOSCIENCE; G 1/08, Tomatoes/STATE OF ISRAEL; G 2/12, Syngenta Participations AG and another v Plant Bioscience Limited; G 2/13, State of Israel - Ministry of Agriculture v Unilever N.V.

12 G 2/12, Syngenta Participations AG and another v Plant Bioscience Limited; G 2/13, State of Israel - Ministry of Agriculture v Unilever N.V., Reasons para IX.

13 See, e.g., European Parliament resolution of 17 December 2015 on patents and plant breeders' rights (2015/2981(RSP)) [2017] OJ C 399/188; proplanta, "Europäisches Patentamt erntet Kritik wegen Bio-Patenten" (proplanta, 18 December 2015) https://www.proplanta.de/agrar-nachrichten/pflanze/europaeisches-patentamt-erntet-kritik-wegen-bio-patenten_article1449552316.html> accessed 11 April 2021; Greenpeace, "Der Brokkoli-Fall," (Greenpeace, 23 October 2014) <https://www.greenpeace.de/sites/www.greenpeace.de/files/publications/fs-fall-brokkoli-30032015.pdf accessed 11 April 2021.

14 Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions [2016] OJ C 411/3.

15 Ibid, paras 1.2, 1.3

16 Notice from the European Patent Office dated 24 November 2016 concerning the staying of proceedings due to the Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [2016] OJ EPO 2016, A104.

and decided almost unanimously on 29 June 2017 that the Implementing Regulations to the EPC should be amended in the sense that plants resulting from essentially biological processes should not be patentable.[17] They introduced the new Rule 28 (2) EPC Implementing Regulations, which entered into force on 1 July 2017 and states:

> *"Under Article 53 (b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.[18]"*

Although this new Rule was intended to serve the purpose of clarifying the meaning of Art. 53 (b) of the EPC, its adoption initially caused further ambiguity.

3. THE PEPPER CASE AND THE REFERRAL TO THE EBA

Soon after the adoption of Rule 28 (2) EPC Implementing Regulations, the TBA was confronted with a new case concerning this new Rule and Art. 53 (b) EPC – the *Pepper*[19] case. In this case, the TBA had to deal with a European patent application relating to new pepper plants and fruits, resulting from an essentially biological process. After the application was rejected by the Examining Division of the EPO on the basis of the new Rule 28 (2) EPC Implementing Regulations, the appellant filed a notice of appeal, maintaining the same claims as before and arguing that the new Rule 28 (2) EPC Implementing Regulations was in contradiction to Art. 53 (b) EPC as interpreted by the EBA in the decision of *Tomatoes II/ Broccoli II*.[20]

The TBA clarified that the meaning of Art. 53 (b) EPC and the meaning of the new Rule 28 (2) EPC Implementing Regulations were in conflict with each other.[21] The EPC should be interpreted in conformity with the interpretation given by the EBA.[22] In this case, this would mean that Art. 53 (b) EPC should be interpreted in accordance with the EBA's decision in *Tomatoes II/ Broccoli II* and that plants obtained from essentially biological processes should therefore be patentable.[23] In contrast, Rule 28 (2) of the EPC Implementing Regulations excludes plants exclusively obtained by means of an essentially biological process from patentability. Since Rule 28 (2) of the EPC Implementing Regulations reverses the meaning of Art. 53 (b) EPC and it is not possible to interpret this Rule in such a way that there is no conflict between these two provisions, the TBA declared Rule 28 (2) of the EPC Implementing Regulations to be void. It further clarified that in case of a conflict between the provisions of the EPC and those of the EPC Implementing Regulations, the provisions of the EPC should prevail, according to Art. 164 (2) EPC.[24]

After the decision of the TBA in the *Pepper* case, at the 159th Meeting of the Administrative Council, the EPOrg Member States and the EPO discussed the need for a solution regarding the patentability of plants obtained from essentially biological processes, as the decision caused legal uncertainty.[25]

Lastly, on 8 April 2019, Mr. Campinos, then-current President of the EPO, handed in a referral to the EBA in accordance with Art. 112 (1) (b) EPC regarding the interpretation of Art. 164 (2) EPC and the assessment of Rule 28 (2) EPC Implementing Regulations.[26] In particular, the EBA was asked to answer the following points of law:

> *"1. Having regard to Art. 164 (2) EPC, can the meaning and scope of Art. 53 EPC be clarified in the Implementing Regulations to the EPC without this clarification being a priori limited by the interpretation of said Article given in an earlier decision of the Boards of Appeal of the Enlarged Board of Appeal?*
>
> *2. If the answer to question 1 is yes, is the exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28 (2) EPC Implementing Regulations in conformity with Art. 53 (b) EPC which neither explicitly excludes nor explicitly allows the said subject-matter?"*[27]

17 The decision was supported by a 36/38 majority of the EPC member states. Only Slovenia abstained and Austria voted against the proposal.

18 Decision of the Administrative Council of 29 June 2017 amending Rules 27 and 28 of the Implementing Regulations to the European Patent Convention (CA/D 6/17) [2017] OJ EPO 2017, A56, Art. 3.

19 Decision of the TBA of 05 December 2018, Extreme dark green, blocky peppers/ SYNGENTA, T 1063/18, ECLI:EP:BA:2018:T106318.20181205.

20 Ibid, para III.

21 Ibid, Reasons para 23.

22 Ibid, Reasons para 21.

23 Ibid.

24 Ibid, Reasons paras 24f., 46.

25 EPO Press Release, "EPO Contracting States discuss next steps regarding the patentability of plants obtained by essentially biological processes" (EPO, 29 March 2019) https://www.epo.org/news-events/news/2019/20190329.html accessed 11 April 2021.

26 EPO, Procedural Documents to Case G 3/19 http://documents.epo.org/projects/babylon/eponet.nsf/0/F3CCF99E734851C1C1258474002CA7E0/$FILE/G_3_19_procedural_documents.pdf accessed 11 April 2021.

27 EPO, Case G 3/19 Referral of a point of law to the Enlarged Board of Appeal by the President of the European Patent Office (Article 112(1)(b) EPC) http://documents.epo.org/projects/babylon/eponet.nsf/0/09D15FA10C1A3A55C125856C0057B988/$File/Referral%20under%20Art.%20112(1)(b)%20EPC_G%2003-19.pdf accessed 11 April 2021.

28 G 3/19, Pepper (follow-up to Tomatoes II and Broccoli II), Reasons para II.4.

29 Ibid, Reasons paras II.5, II.6, III.

30 Ibid, Reasons para XXVI.8.

31 Ibid, Reasons para XIX.

32 Ibid, Reasons para XX.

33 Ibid.

34 Ibid.

35 Rules of Procedure of the Boards of Appeal, in force from 1 January 2020, Decision of the Administrative Council of 26 June 2019 approving the revised version of the Rules of Procedure of the Boards of Appeal (CA/D 5/19 Corr. 1) [2019] OJ EPO 2019 A/63.

36 G 3/19, Pepper (follow-up to Tomatoes II and Broccoli II), Reasons para XX.

37 Ibid, Reasons para XXI.

38 Ibid, Reasons para XXII.

39 Ibid, Reasons paras XXIII, XXIV.

40 Ibid, Reasons para XXVI.

41 In the vote, 35 Contracting States voted for the adoption of Rule 28 (2) EPC Implementing Regulations, 1 Contracting State voted against it, 1 Contracting State abstained and 1 Contracting State was not present. See Minutes of the 152nd Meeting of the Administrative Council of 28 and 29 June 2017, CA/PV 152.

42 G 3/19, Pepper (follow-up to Tomatoes II and Broccoli II), Reasons para XXVI.5.

The first referred question obviously aims to get clarification in the matter of the internal hierarchy of the individual organs within the EPOrg. In particular, whether the Rules of the EPC Implementing Regulations or the decisions of the EBA take precedence. The second question ultimately aims at the substantive interpretation of the exception in Art. 53 (b) EPC. Just over a year after the referral was handed in, on 14 May 2020, the EBA published its opinion.

4. DECISION OF THE EBA ON THE REFERRAL IN THE PEPPER CASE

4.1 Clarification of the scope of the referral

In its decision, the EBA first clarified the scope and focus of the referral and emphasized that only the second question of the President of the EPO reflected the real purpose of the referral, namely the intention to ask the EBA to review its interpretation of Art. 53 (b) EPC given in the decision *Tomatoes II/Broccoli II*, and conclude that this interpretation should be abandoned.[28] The first question, however, was too general and unspecific in its wording and raised an institutional issue, which went beyond the original intention of the referral. Therefore, the EBA combined the two referred questions of the President of the EPO into one single, rephrased question, considered to reflect the real intention of the referral.[29] The rephrased question that the EBA addressed in its opinion was:

> *"Taking into account developments that occurred after a decision by the Enlarged Board of Appeal giving an interpretation of the scope of the exception to patentability of essentially biological processes for the production of plants or animals in Article 53(b) EPC, could this exception have a negative effect on the allowability of product claims or product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process feature define an essentially biological process?"*

Due to the reformulation of the question, the decision focused mainly on the substantive question of the subject-matter of the exclusion set out in Art. 53 (b) EPC.

4.2 Dynamic interpretation

In answering the reformulated question, the EBA first abandoned the interpretation of Art. 53 (b) EPC given in its decision in *Tomatoes II/Broccoli II* and stipulated that Art. 53 (b) EPC must now be interpreted and applied against the background of the introduction of Rule 28 (2) EPC Implementing Regulations. This would mean that it should now be interpreted as excluding products obtained from essentially biological processes, as well as essentially biological process features defining an essentially biological process, from patentability.[30] This opinion was based on a dynamic interpretation of Art. 53 (b) EPC in the light of Rule 28 (2) EPC Implementing Regulations.

Further, the EBA stated that Rule 28 (2) EPC Implementing Regulations was not taken into account in the decision of the TBA in the *Pepper* case, when interpreting Art. 53 (b) of the EPC. The decision of the TBA seemed to rest upon the perception that the EBA gave a final interpretation of the scope of Art. 53 (b) EPC in *Tomatoes II/ Broccoli II* and only a formal amendment of the EPC itself could overturn this interpretation.[31] However, the EBA stated that such a perception was not supported either by the EPC itself or by any general legal principle.[32] Furthermore, the EBA took the view that such a perception would be too strict, taking into account that Art. 53 (b) EPC had been acknowledged to be open to interpretation. Moreover, a subsequently adopted Rule, deviating from an interpretation of an Article of the EPC by the BoA, should not per se be *ultra vires*.[33] The EBA clearly stated that a

> *"particular interpretation which has been given to a legal provision can never be taken as carved in stone, because the meaning of the provision may change or evolve over time."*[34]

This view was based on Art. 21 of the Rules of Procedure of the Boards of Appeal (RPBA) 2020[35]. Art. 21 of the RPBA 2020 stipulates that a Board has to refer a question to the EBA in accordance with Art. 112 (1) EPC, if it considers it necessary to deviate from an interpretation or explanation of the Convention contained in an earlier decision or opinion of the EBA. However, such a referral would be pointless if the EBA would not then have the possibility to revise an earlier decision on that specific point of law.[36]

Accordingly, the interpretation of a provision, even if it has already been the subject of a decision given by the EBA, may still be the subject to later developments, whether they are legal, practical or factual.[37]

This view resulted in the EBA applying a dynamic interpretation in the referral. Such a method of interpretation should be used if considerations had arisen since the EPC was signed providing reason to believe that a literal interpretation of a provision was in contradiction of the legislator's objective.[38] Although the EBA acknowledged that Art. 53 (b) EPC had remained almost unamended since the drafting of the EPC, it nevertheless stated that it could not, while interpreting Art. 53 (b) EPC, ignore the decision of the Administrative Council to adopt Rule 28 (2) of the EPC Implementing Regulations.[39] Subsequently, the EBA analyzed whether and to what extent this would justify a dynamic interpretation of Art. 53 (b) EPC.[40] In the view of the EBA, the result of this analysis was that such a dynamic interpretation was justified by the voting behavior of the Contracting States represented in the Administrative Council, when amending Rule 28 (2) EPC Implementing Regulations. The vast majority of the Contracting States voted in favor of the introduction of Rule 28 (2) of the EPC Implementing Regulations, which showed that the intentions and aims of the Contracting States with regard to Art. 53 (b) of the EPC had evolved since the decision in *Tomatoes II/Broccoli II*.[41] This was also confirmed by the adaptation of national provisions to the contents of Rule 28 (2) of the EPC Implementing Regulations.[42]

The intention of the Contracting States to exclude from patentability products obtained from essentially biological processes should also not be incompatible with the wording of Art. 53 (b) of the EPC, since it is broad and allows such an interpretation.[43] The EBA therefore ultimately concluded that a dynamic interpretation of Art. 53 (b) of the EPC was permitted and even necessary, given the clear legislative intention of the Contracting States represented in the Administrative Council.[44]

In conclusion, Art. 53 (b) of the EPC is now interpreted as excluding from patentability products obtained from essentially biological processes, as well as essentially biological process features defining an essentially biological process.[45]

4.3 Lack of clarification concerning the institutional conflict

Concerning the original first referred question of the President of the EPO, which aimed at clarifying the question of the internal hierarchy of the individual organs within the EPOrg, the EBA was reluctant to give a clear answer. This might be due to the rephrasing of the questions submitted, with the rephrased question focusing solely on the interpretation of Art. 53 (b) of the EPC.

In respect of the institutional dispute, the EBA therefore merely stated that, due to the special structural organization and constitution of the EPOrg, it could not find any reason to believe that the adoption of Rule 28 (2) of the EPC Implementing Regulations by the Administrative Council violated the doctrine of separation of powers or infringed upon the essentiality theory ("Wesentlichkeitsprinzip"), originating from German constitutional law.[46] The latter states that decisions of fundamental or essential importance are reserved for the Parliament as the legislative branch and may not be made by administrative organs through administrative regulations.[47]

The EBA describes the EPOrg as an intergovernmental organization, founded under international law by the Contracting States, and governed by the rule of law.[48] The principles underlying the rule of law have generally been adopted by the Contracting States at the national level.[49] However, these principles – and in particular their scope and their implementation – must reflect the organizational structure of the EPOrg and its specific nature.[50] Art. 4 (2) of the EPC provides that the EPOrg has two organs, namely the EPO and the Administrative Council. According to Art. 4 (3) of the EPC, the EPO's task is to grant European patents under the supervision of the Administrative Council. Both institutions therefore have an executive function in this respect.[51]

According to the EBA, the BoA have the role of an independent judiciary in the European patent system.[52] Although they form a separate organizational unit with organizational autonomy, they are not an organ of the EPOrg, but rather only structurally integrated into the EPOrg in accordance with Art. 15 of the EPC. In particular, the EBA emphasized that the EPOrg does not have its own parliament, which corresponds to a legislature that is part of the constitutional arrangements of the Contracting States.[53]

Further, on the one hand, it cannot be deduced from the principle of separation of powers that there is a general prohibition on adopting secondary legislation – in this case, Rule 28 (2) of the EPC Implementing Regulations – which concerns the interpretation of primary legislation given by the EBA – here, Art. 53 (b) of the EPC.[54]

On the other hand, due to the fact that the EPOrg does not have its own parliament, the essentiality theory cannot be applied directly.[55] However, even if the essentiality theory would suggest that Art. 53 (b) of the EPC could be amended only by a Diplomatic Conference in accordance with Art. 172 of the EPC, such an assumption would be too restrictive. It would disregard the fact that the Administrative Council can amend Art. 53 (b) of the EPC within the scope of its powers under Art. 33 (1) (b) of the EPC and Art. 35 (3) of the EPC.[56]

However, the EBA noted that both of the aforementioned considerations were no longer related to the point of law that formed the basis of the proposal after the rephrasing of the referred question, as it was exclusively directed at a potential new interpretation of Art. 53 (b) of the EPC by the EBA, in its function as an independent judicial organ in accordance with Art. 112 (1) of the EPC.[57]

In view of the particular structural organization and constitution of the EPOrg, the EBA therefore could not find any foundation to believe that the adoption of Rule 28 (2) of the EPC Implementing Regulations by the Administrative Council violated the principle of separation of powers or infringed upon the essentiality theory.[58]

5. LEGAL EVALUATION OF THE DECISION

It remains debatable how the decision of the EBA should be evaluated from a legal perspective. In this respect, a distinction must be made between the conflict regarding the subject-matter, i.e., the interpretation of Art. 53 (b) of the EPC, and the institutional conflict.

5.1 Evaluation of the dynamic interpretation of Art. 53 (b) EPC

The patent situation for plants obtained from essentially biological processes, prior to the issuance of the EBA's opinion on the referral, seemed to be more favorable for international corporations or large seed companies, who could easily obtain patents for and thus rights to plants that had been bred by farmers over centuries.[59] The risk for the smaller breeders in Europe was that these large seed companies would gain a dominant position on the market for plant-related products.[60]

The decision of the EBA in the *Pepper* case marked a turning point in legal practice. In order to evaluate whether the new interpretation of Art. 53 (b) of the EPC might lead to a fair balance between the individual parties for which the question of the patentability of products obtained from essentially biological processes plays a role, these interests must first be identified.

5.1.1. Interests of large seed companies

On the one hand, large seed companies have a great interest in getting patents for products obtained from essentially biological processes.[61] A few large companies dominate the global seed trade and also own most of the patents relating to vegetables and have filed the most such patent applications with impact in the EU.[62] These large seed companies invest a lot of time and money in the development of new, genetically modified foods. For biotechnological inventions, the average development time is around 13 years and the average development cost amounts to US$ 136 million.[63] The companies expect to get something in return for such investments.[64] This is also one of the justifications behind the patent system: the contribution of an inventor should be recognized through the granting of a reward.[65] In the case of a patent, the large seed companies are able to monetize their intellectual property rights by licensing their inventions or parts of their inventions to each other, smaller seed companies and farmers or public breeding programs.[66]

5.1.2. Interests of smaller breeders

On the other hand, the interests of smaller breeders need to be taken into account, which means that the protection of intellectual property rights must be balanced against the right of free access to natural materials.[67] The aim behind the exclusion set out in Art. 53 (b) of the EPC is to keep naturally occurring materials in the public domain, as they should be freely accessible for everyone, especially scientists and breeders.[68] Further, it should also secure the freedom to operate for competitors and suppliers.[69] This creates arguments in favor of smaller plant breeders.

A protection of products obtained from essentially biological processes might lead to a stagnation of the innovative process. In order to create new plants and genetically modified food, breeders need to have access to existing natural materials. Without such access, it would be impossible for breeders to develop new plants, including plants obtained from essentially biological processes.[70] The number of patent applications relating to vegetables has increased in the last few years.[71] If more patents were to be granted, this would lead to even more limited availability of material for plant breeders.[72] Moreover, the granting of more patents related to plants would create several problems for plant breeders. First, it is often unclear what biological material is covered by a patent.[73] This results from the fact that the scope of a claim cannot

43 Ibid, Reasons para XXVI.6.
44 Ibid, Reasons para XXVI.7.
45 Ibid, Reasons para XXVI.8.
46 Ibid, Reasons para XXV.3.
47 Ibid, Reasons para XXV.
48 Ibid, Reasons para XXV.1.
49 Ibid.
50 Ibid, Reasons para XXV.2.
51 Ibid.
52 Ibid.
53 Ibid.
54 Ibid, Reasons para XXV.3.1.
55 Ibid, Reasons para XXV.3.2.
56 Ibid.
57 Ibid, Reasons paras XXV.3.1, XXV.3.2.
58 Ibid, Reasons para XXV.3.
59 Ana Nordberg, Timo Minssen, Sune Holm, Maja Horst, Kell Mortensen and Birger Lindberg Møller, "Cutting edges and weaving threads in the gene editing revolution: reconciling scientific progress with legal, ethical, and social concerns" [2018] 5 (1) Journal of Law and the Biosciences 35, 68; The GREENS/EFA in the European Parliament, "The European Patent Office's New Rules Are Unacceptable – Patents on 'Natural' Seeds" (The GREENS/EFA in the European Parliament, 29 June 2017) https://www.greens-efa.eu/en/article/news/the-european-patent-offices-new-rules-are-unacceptable/ accessed 11 April 2021.
60 Michael Blakeney, Intellectual Property and Food Security (Wallingford (Oxfordshire), Cambridge 2009) 15; Thaleia Karampaxoglou, "Genetically Modified Food and Crops: Risks and Intellectual Property Rights" [2015] Centre for Applied Ethics, Linköping University, 20 https://www.diva-portal.org/smash/get/diva2:826858/FULLTEXT02 accessed 11 April 2021.
61 Blakeney (n 60) 15.
62 Michael A Kock and Floris ten Have, "The 'International Licensing Platform-Vegetables': A prototype of a patent clearing house in the life science industry" [2016] 11 (7) Journal of Intellectual Property Law & Practice 496, 502; Jason Zhang, "Top 20 Global Seed Companies in 2018 – Two megacorps, Four supercorps and Differentiated Development" [2019] AgroPages 2019 Market Insight, http://news.agropages.com/News/NewsDetail---32780.htm accessed 11 April 2021.
63 Philips McDougall, "The Cost and Time Involved in the Discovery, Development and Authorisation of a New Plant Biotechnology Derived Trait, A Consultancy Study for Crop Life International" (2011) R&D Study 7, 11 https://croplife.org/wp-content/uploads/2014/04/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf accessed 11 April 2021.
64 Kock and ten Have, "The 'International Licensing Platform-Vegetables'" (n 62) 497; Kock, "Patents for Life" (n 2) 230.
65 Lionel Bently, Brad Sherman, Dev Gangjee and Philip Johnson, Intellectual Property Law (5th edn, Oxford University Press 2018) 397.
66 Elizabeth I Winston, "What If Seeds Were Not Patentable?" [2008] 2008 (1) Michigan State Law Review 321, 330; Elizabeth A Rowe, "Patents, Genetically Modified Foods, and IP Overreaching" [2011] 64 (3) SMU Law Review 859, 866.
67 Kock and ten Have, "The 'International Licensing Platform-Vegetables'" (n 62) 497; Kock, "Patents for Life" (n 2) 233.
68 Christine Godt, "Technology, Patents and Markets: The Implied Lessons of the EU Commission's Intervention in the Broccoli/Tomatoes Case of 2016 for Modern (Plant) Genome Editing" [2018] 49 (5) International Review of Intellectual Property and Competition Law 512, 526.
69 Ibid.
70 Kock and ten Have, "The 'International Licensing Platform-Vegetables'" (n 62) 497.
71 Ibid, 502.
72 Ibid, 504; Kock, "Patents for Life" (n 2) 233.
73 Godt (n 68) 526; Li Jiang, "Commercialization of the gene-edited crop and morality: challenges from the liberal patent law and the strict GMO law in the EU" [2019] 39 (2) New Genetics and Society 191.

be identified beyond doubt and that there is no official requirement for patent marking.[74] As a consequence, breeders must be extremely careful, since the mere integration of a single patented trait, even when inadvertently used in a complex breeding process, can constitute a patent infringement. As most of the patents belong to a small number of large international seed companies, not only small farmers are affected by this, but also other stakeholders in the food supply chain.[75] Moreover, this uncertainty for breeders is enhanced by the length of patent examination processes, which often extend over several years. Further, the differences in national patent laws can lead to increased uncertainty among breeders regarding the status of biological material they want to use, since those differences may result in there being a multitude of patent claims for the same trait.[76] Thus, the situation at hand before the decision in the referral posed a fundamental threat and was seen to cause a stagnation of innovation in the field of breeding.[77]

Moreover, as already stated, the market power of large seed companies places a heavy burden on small farmers. In case of a patent granted to a large seed company, small farmers might have to pay for a seed license or to use certain traits of a new plant. They would thus be dependent on the large companies, which would be able to dictate prices on the concentrated market. Ultimately, this could lead to bankruptcy for small breeders.[78]

5.1.3. Balance of interests and harmonization of law

When reviewing the arguments of the different parties involved, it is difficult to give a clear answer to the question whether products obtained from essentially biological processes should be patentable, as two major interest groups are facing each other. Nevertheless, the decision of the EBA should be evaluated positively in this regard.

The decision clearly represents a setback for those applying for plant patents, which are mostly large seed companies. However, first, it should be kept in mind that the new dynamic interpretation of Art. 53 (b) of the EPC has no retroactive effect on European patents, containing product claims or product-by-process claims, which were granted before 1 July 2017, the date when Rule 28 (2) of the EPC Implementing Regulations entered into force.[79] The same applies for pending European patent applications which were filed before that date, as the relevant date for applications is the date of filing or, if priority has been claimed, the priority date.[80] Second, the decision of the EBA does not rule out the patentability of genome-edited plants in general. Rather, only plants or plant products obtained solely by essentially biological processes remain excluded from patentability. As long as the breeding process contains a significant step of a technical nature, performed within the steps of sexual crossing and selecting, the process might still be patentable.[81] Third, the pressure that can be placed on the shoulders of smaller farmers, and probably also on the entire food chain, if a large number of patents on vegetables or other plant products are granted, will grow steadily. It is of particular concern, also from an antitrust perspective, that a few larger companies may control entire food chains.

Moreover, it should also be remarked that products obtained from essentially biological processes should be included in the exemption of Art. 53 (b) of the EPC, as any other interpretation would undermine the entire meaning of Art. 53 (b) of the EPC.[82] If essentially biological processes are excluded from patentability, but patents on plants obtained from such processes are allowed, the exclusion of these processes would be rendered ineffective.[83] A patent for a process covers all products manufactured through that process.[84] By contrast, a patent for a product covers only the protection for the product.[85] If Art. 53 (b) of the EPC excludes essentially biological processes from patentability, this exclusion would encompass products resulting from these processes.[86] However, if a product obtained from an essentially biological process could get patent protection, this would be contradictory to the fact that products are excluded from patentability within the exclusion for essentially biological processes, which would undermine the entire meaning of Art. 53 (b) of the EPC.[87]

Further, the argument of the harmonization of law plays an important role in coming to a final decision on the question of the patentability of products obtained from essentially biological processes. The fact that the interpretation of Art. 53 (b) of the EPC might differ from the interpretation of Art. 4 (2) of the BD places a heavy burden on states that are Member States of the EU and also Contracting States of the EPC. They would always risk violating their duties under one of the Regimes, if these provisions differ from each other. An interpretation of the EPC in accordance with EU law is therefore useful to ensure a functioning economic market in Europe.[88]

Thus, the decision of the EBA in *Pepper* is to be welcomed in regards to the subject-matter, as the risk of a monopoly position for large seed companies should be avoided in order to allow smaller breeders to remain competitive. Above all, however, a harmonization of the EPC and the BD is necessary, to avoid a breach of duty on the part of the EU Member States. Otherwise, they would be condemned to violate one or the other of the two patent systems.

5.2. Dispute concerning the institutional conflict

Even if the decision of the EBA should be welcomed from a content-related point of view, the dispute concerning the subject-matter should be strictly separated from the institutional questions that the referral raised. In this respect, however, the EBA did not reach a decision. In fact, it appeared that the EBA avoided resolving the institutional conflict through reformulation of the referred questions.[89] However, the statement of the EBA – that the doctrine of separation of powers was not violated by the amendment of Rule 28 (2) EPC Implementing Regulations – could be considered critical. This becomes more evident when analyzing the general roles of the BoA and the EBA, as well as the general role of the Administrative Council.

5.2.1. Roles of the different institutions within the EPO

According to Art. 4 (2) of the EPC, the EPOrg has two organs: the EPO and the Administrative Council.

Within the EPO, the BoA consist of the EBA, the Legal Board of Appeal, the Disciplinary Board of Appeal and 28 TBAs.[90] The BoA, and therefore the EBA, have a quasi-judicial function. According to Art. 21 to 23 of the EPC, they act as an independent judiciary.

On the one hand, it has to be kept in mind that the BoA are not organs of the EPOrg. This means that they are not, formally, at the same level as the Administrative Council.[91] On the other hand, they are not entirely outsourced to the EPOrg as a form of individual judicial organ.[92] Thus, the EPC does not grant the BoA a general competence to review all legal acts of the EPOrg.

However, the European Court of Human Rights and national courts recognize the independent judicial status of the BoA and the EBA.[93] Moreover, the EBA itself underlines that the EPOrg is based on the principle of separation of powers, with the EPC granting the executive power to the EPO, the legislative power to the Administrative Council and the role of an independent judiciary to the EBA, despite its structural integration in the EPOrg.[94]

As the aforementioned structural weaknesses were apparently in conflict with the intention of the EPOrg, its Member States and the BoA themselves to upgrade them to full courts, the President of the EPO initiated further reforms in March 2016, which entered into force on 1 July 2016.[95] This reform package means that the BoA form a separate organizational unit and are headed by the President of the BoA, who is hierarchically independent from the President of the EPO and accountable only to the Administrative Council.

The Administrative Council is an individual organ of the EPOrg, pursuant to Art. 4 (2) (b) of the EPC. The legislative function of the Administrative Council can be gleaned from Art. 33 of the EPC, as it is, for example, competent to amend parts of the EPC or the Implementing Regulations. Hence, the Administrative Council can also be described as the legislative organ of the EPOrg.[96] However, it is not correct to assume that the Administrative Council is a fully-fledged legislative organ, as it is missing democratic legitimacy and control from a constitutional point of view.[97] Under Art. 172 EPC, the only authority competent to revise the provisions of the EPC is a Diplomatic Conference of the Contracting States. Moreover, if the Administrative Council would be regarded as a fully-fledged legislative organ, the principle of primacy of law would lead to the conclusion that the Rules of the Implementing Regulations adopted by said council would be binding and understood as legally binding laws for all the institutions of the EPOrg, including the BoA and the EBA.[98] Consequently, it seems to be more consistent to assume that the Administrative Council acts in an executive capacity when adopting new Rules of the Implementing Regulations in the sense of setting subordinate, interpretative standards.[99] This is also supported by the fact that the power of the Administrative Council to amend the Implementing Regulations is limited by Art. 164 (2) of the EPC, which mandates the priority of the provisions of the EPC over the Rules of the Implementing Regulations in case of a conflict. The adjustments to the Implementing Regulations made by the Administrative Council must therefore remain within the framework of the EPC and thus within the framework of substantive, democratically legitimated patent law.[100] Consequently, when the Administrative Council adopted Rule 28 (2) EPC Implementing Regulations, it was acting as an executive organ that sets standards.[101]

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74 Michael A Kock and Herbert Zech, "Pflanzenbezogene Erfindungen in der EU – aktueller Stand" [2017] 119 (10) Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 1004, 1012; Kock, "Patents for Life" (n 2) 234.

75 Timo Minssen and Ana Nordberg, "The Impact of 'Broccoli II' and 'Tomatoes II' on European Patents in Conventional Breeding, GMOs, and Synthetic Biology: The Grand Finale of a Juicy Patents Tale?" [2015] 34 (3) Biotechnology Law Report 81, 96; Jiang (n 73) 191.

76 Kock and ten Have, 'The "International Licensing Platform-Vegetables"' (n 62) 504.

77 Ibid.

78 Karampaxoglou (n 60) 20ff.; Jiang (n 73) 191.

79 G 3/19, Pepper (follow-up to Tomatoes II and Broccoli II), Reasons para XXIX.

80 Ibid.

81 See G 2/07, Broccoli/PLANT BIOSCIENCE; G 1/08, Tomatoes/STATE OF ISRAEL, Reasons para 6.4.2.3.

82 No patents on seeds!, amicus curiae brief G 3/19 (30 September 2019) 4f. http://documents.epo.org/projects/babylon/eponet.nsf/0/0DFBAF29B5CB8798C12584700305CF7/$File/Npos_Amicus%20Curiae%20letter%20on%20G3_19.pdf accessed 11 April 2021; The Danish Government, amicus curiae brief G 3/19 (30 September 2019) para 29 http://documents.epo.org/projects/babylon/eponet.nsf/0/5ADBCD9142BC86CEC12584870030AA06/$File/The%20Danish%20Governments%20amicus%20curiae%20submission%20in%20case%20G%203.19.pdf accessed 11 April 2021.

83 No patents on seeds!, amicus curiae brief G 3/19 (n 82) 4; The Danish Government, amicus curiae brief G 3/19 (n 82) para 29.

84 Art. 64 (2) EPC.

85 No patents on seeds!, amicus curiae brief G 3/19 (n 82) 4.

86 Ibid.

87 The Danish Government, amicus curiae brief G 3/19 (n 82) para 29.

88 Josepha Koch, "G 3/19 - The Struggle for Power Within the EPC" [2020] 69 (10) Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 1027, 1031.

89 Aloys Hüttermann, "Die Entscheidung G 3/19 oder die Kunst der autoritätswahrenden Konfliktlösung (?)" [2020] 111 (6) Mitteilung der Deutschen Patentanwälte 255, 257.

90 EPO, About the Boards of Appeal https://www.epo.org/law-practice/case-law-appeals/about-the-boards-of-appeal.html accessed 11 April 2021.

91 Maximilian Haedicke, "Das Verhältnis zwischen der Rechtsprechung der Beschwerdekammern und nachträglich erlassenen Regeln der Ausführungsordnung zum EPÜ" [2019] 68 (10) Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 885, 890.

92 Ibid.

93 Ibid; CA/16/15 Proposal for a structural reform of the EPO Boards of Appeal of the 06 March 2015, para 5.

94 Opinion of the EBA of 12 Mai 2010, Programs for computers, G 3/08, ECLI:EP:-BA:2010:G000308.20100512, para 7.2.1.

95 CA/16/15 (n 93); CA/D 6/16 Decision of the Administrative Council of 30 June 2016 amending the Implementing Regulations to the European Patent Convention [2016] OJ EPO 2016, A100; CA/D 7/16 Decision of the Administrative Council of 30 June 2016 setting up a Boards of Appeal Committee and adopting its Regulations [2016] OJ EPO 2016, A101.

96 Tobias H Irmscher and Alfons Schäfers, "Comment on certain Articles of the EPC," in: Georg Benkard, Europäisches Patentübereinkommen (3rd edn, C H Beck, 2019) Art. 33 para 3.

97 Ibid, Art. 26 para 4; Koch (n 88) 1029.

98 Haedicke (n 91) 890.

99 G 3/08, Programs for computers, para 7.2.1; Irmscher and Schäfers (n 96) Art. 33 para 3.

100 Koch (n 88) 1029.

101 Haedicke (n 91) 890.

5.2.2. Separation of powers and mechanism of "checks and balances"

As has been shown, the system of institutions within the EPOrg is relatively clear: the Administrative Council only formally forms the legislative branch, but it does not make substantive patent law, as a Diplomatic Conference of the Contracting States is needed for that in accordance with Art. 172 EPC.[102] It also acts in an executive function when amending the EPC Implementing Regulations. The BoA, in contrast, act as a quasi-judicial branch, while the process of patent examination represents the executive branch.[103] This separation is plausible, as the BoA are better placed to find an optimal interpretation of the provisions of the EPC, since the Administrative Council is subject to political influence.[104] Hence, there could be a risk that political interests would prevail if the Administrative Council were empowered to interpret the provisions. Therefore, the system of the separation of powers would be undermined if the Administrative Council had the competence to overrule decisions of the BoA, in particular of the EBA.

Further, the patent system and its effective formal interactions are the result of the mechanism of "checks and balances" between the different institutions involved.[105] The term "checks and balances" takes into account the totality of the formal power structures in a governmental system, created by the formal mutual dependence of the individual organizations on each other.[106] The separation of powers into legislative, executive and judicial branches is the most effective regime in the system of "checks and balances," as it guarantees the independence of the judiciary.[107] The system of separation of powers does not mean that the different branches are strictly separated from each other. All institutions are interdependent and respect each other and their respective competences.[108] However, in so far as possible, the different tasks should be performed in the most appropriate manner, which means by the institutions which are best placed in terms of their function, composition and procedures.[109] Moreover, the system of separation of powers is not tailored to national government, but can be applied to any international organization.[110]

Hence, the system of "checks and balances" suggests that the BoA, not the Administrative Council, should interpret the provisions of the EPC. Since this system provides for respecting the decisions of the other institutions, this should also apply within the EPOrg, even if this implies a duty of compromise and self-restraint.[111] This is further supported by the reform package regarding a more independent position of the BoA, which entered into force in 2016, as it showed that the independence of the judiciary should be promoted within the EPOrg.[112] Consequently, it would be desirable to have an informal binding effect, leading the Administrative Council to recognize the decisions of the EBA and be *de facto* bound by them. The mere assessment of the Administrative Council that a decision of the EBA is politically inopportune is therefore not sufficient to allow it to interfere with the tasks that the EBA carries out under its own responsibility.[113]

However, such a situation emerged in the *Pepper* case and the events that led to the amendment of Rule 28 (2) of the EPC Implementing Regulations. It appeared as a daring legal construction, since the amendment was based on a Notice of the European Commission, with no legally binding effect, and which – at least at the time of the amendment – was contrary to the EBA's case law in *Tomatoes II/Broccoli II*. Further, by reformulating the referred questions, the EBA skillfully avoided the institutional issues of the case. However, not only were important institutional issues avoided; former legal acts that might not have been legitimate were not discussed and thus may even, indirectly, have been accepted. On the one hand, it remains unclear whether the introduction of Rule 28 (2) of the EPC Implementing Regulations by the Administrative Council was possible, as it was in conflict with the case law of the EBA at the time. On the other hand, it also remains open whether the TBA was entitled to declare Rule 28 (2) of the EPC Implementing Regulations invalid or whether this is a privilege of the EBA.[114]

Further, even if the EBA managed – which it also explicitly stated – not to directly violate the aforementioned doctrine of separation of powers and the mechanism of "checks and balances" in the current decision, it seemed that it was not able to withstand the political pressure from the EU. The EBA has clearly stated that the Administrative Council has no *"carte blanche"* to change the case law of the EPO at its discretion.[115] However, this may be the first time that an EBA has directly reversed its own previous case law. This suggests that the EBA ultimately bowed to political pressure from the EU and its amendment of Rule 28 (2) EPC Implementing Regulations, and pressure from the EPO President. The EU was thus the winner in this conflict and the EBA does seem to be allowing itself to be politically influenced.[116] This may have opened the door for the EU to exert political pressure on the EPO to force a change in case law. Furthermore, this case can be used in later referrals or appeals, to argue that any decision by the EBA is open to re-evaluation.

Ultimately, the EBA was able to abandon its own case law, giving the EU and the Member States justice, and still maintain its own authority to a certain extent by reformulating the questions referred for a preliminary ruling. Nevertheless, its independence from and the influence of the EU, the Administrative Council and the EPO President, can be questioned – and thus the mechanism of "checks and balances" within the EPO can also be questioned.

6. CONCLUSION

The pepper on our plate – who owns it? A clear answer to this question has been awaited for several years and was now finally provided by the EBA in its opinion on the referral in the *Pepper* case. However, this referral turned out to be much more complex than initially assumed. It raised many follow-up questions, which not only concerned the implications of the amendment of Rule 28 (2) of the EPC Implementing Regulations on the interpretation of the exception in Art. 53 (b) of the EPC, but also called into question the power structure within the EPOrg.

With regard to the substantive conflict on the interpretation of Art. 53 (b) EPC, the decision of the EBA should be welcomed. It seems preferable to interpret the provision in accordance with the contents of Rule 28 (2) EPC Implementing Regulations, especially in order to create a harmonization of the EPC and the BD. It seems unacceptable that states, which are both Member States of the EU and Contracting States of the EPC, should be forced to violate their obligations under one of the systems. This would create permanent legal uncertainty. Thus, it is ultimately favorable to interpret Art. 53 (b) of the EPC as provided under Rule 28 (2) of the EPC Implementing Regulations. As the EBA relies on a dynamic interpretation of Art. 53 (b) EPC and clarifies that a previous decision of the EBA should never be considered to be set in stone, since the meaning of a provision may change over time, it becomes clear that a decision once given by the EBA does not automatically constitute a final interpretation of a provision. Hence, it can be seen that the amendment of Rule 28 (2) of the EPC Implementing Regulations affects the interpretation of Art. 53 (b) of the EPC to the extent that it provides the basis for the new, dynamic interpretation of this provision. Although the amendment does not directly deprive past decisions of the EBA of their binding effects, it leads to a departure from previous case law.

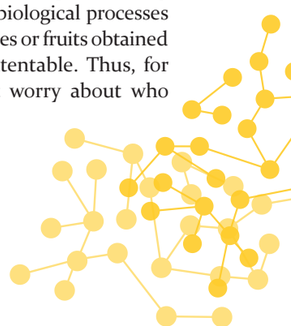
However, though the new interpretation of Art. 53 (b) of the EPC seems favorable, the amendment of Rule 28 (2) of the EPC might not have been in conformity with the internal hierarchy of the EPC and the EPOrg.

In respect to the institutional conflict the referral raised, the EBA did not provide a clear answer. Hence, the question of hierarchy within the EPO remains unanswered. Further, it remains unresolved whether the TBA was empowered to overrule Rule 28 (2) of the EPC Implementing Regulations in *Pepper* and how the relationship between the case law of the EBA and the amendments of the EPC Implementing Regulations by the Administrative Council is structured. The EBA managed to avoid these matters by using the trick of reformulating the referred questions, which seems to have been the easiest way to find a solution to the ongoing dispute regarding the interpretation of Art. 53 (b) of the EPC. On the other hand, this might call the EBA's political independence into question.

The full impact of the opinion cannot yet be foreseen. But what is certain is that the EPC and the BD were harmonized with regard to the exclusion for essentially biological processes for the production of plants, at least for now. Further, the extension of the exemption set out in Art. 53 (b) of the EPC will probably lead to an increased reliance on other forms of protection in this area, such as plant variety protection. Moreover, even though the EBA does not directly take a position on the adoption of Rule 28 (2) of the EPC Implementing Regulations, it seems that the decision gives the Administrative Council the opportunity to amend the EPC in the future by simply introducing new Rules to the EPC Implementing Regulations. This raises the question whether the EBA truly acts as an independent organ of the EPO, free from political influence by the Administrative Council or the President of the EPO.

As the dispute about the interpretation of the exemption for essentially biological processes set out in Art. 53 (b) of the EPC has already been going on for several years, it is to be expected that the opinion of the EBA will spark controversy again at some point and it seems unlikely that the debate on the patentability of plants obtained from essentially biological processes will lose its momentum. New legal issues might arise, given the always evolving biotechnology sector.

However, at least for now, the question of patentability of products obtained from essentially biological processes has been clarified. Accordingly, vegetables or fruits obtained from said processes are no longer patentable. Thus, for the foreseeable future, we need not worry about who owns the pepper on our plate.



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[102] Ingrid Schneider, "Governing the patent system in Europe: The EPO's supranational autonomy and its need for a regulatory perspective" [2009] 36 (8) Science & Public Policy 619, 622.

[103] Ibid, 622f.

[104] Haedicke (n 91) 894.

[105] Susana Borrás, "The governance of the European patent system: effective and legitimate?" [2006] 35 (4) Economy and Society 594, 600.

[106] Ibid.

[107] Kathrin Klett, "Neuorganisation der Beschwerdekammern in der Europäischen Patentorganisation" [2017] (3) sic! 119 https://www.sic-online.ch/fileadmin/user_upload/Sic-Online/2017/documents/119.pdf accessed 11 April 2021.

[108] Ibid.

[109] Haedicke (n 91) 893.

[110] Klett (n 107) 120.

[111] Haedicke (n 91) 894.

[112] The question of whether this reform package is democratically viable under the rule of law and whether it actually creates complete independence for the BoA is viewed critically, see Klett (n 107) 316; Siegfried Broß, "Die Patenterteilungspraxis nach dem EPÜ – Erosion des Rechtsstaates?" [2017] 66 (8-9) Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 670-674.

[113] Haedicke (n 91) 894.

[114] For more information on this issue, see: Aloys Hüttermann, "Who decides if there is a conflict between Implementing Regulations and Articles of the European Patent Convention?" [2019] 14 (12) Journal of Intellectual Property Law & Practice 958–963.

[115] G 3/19, Pepper (follow-up to Tomatoes II and Broccoli II), Reasons para II.5.

[116] Hüttermann, "Die Entscheidung G 3/19" (n 89) 257; Koch (n 88) 1030f.

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The development of the CJEU case law in plant variety rights

By Roberto Manno

ABSTRACT

Plant Variety Rights (or Plant Breeders Rights) involve fundamental aspects of day-to-day life "not limited" to food consumption, access to biodiversity, safeguard of agriculture, incentive of varietal improvement to the benefit of society. The present article will (try to) offer an excursus of the recent developments in the EU case law, assessing the particular regime of Plant Breeders Rights, especially with regard to "traditional" rights as Patents, Trademarks and Designs, with reference to the Judgments of the General Court and the Court of Justice of European Union according to the rules set forth in the EU Regulation No. 2100/94 the International Union for the Protection of New Varieties of Plants.

1.1 INTRODUCTION

After EU Trademarks and designs, the Community Plant Variety Rights (hereinafter, "CPVRs" or, also, "PVRs") are the second kind of EU-wide IP rights[1]. The legal basis for this is Council Regulation (EC) No. 2100/94 on Community plant variety rights (co-called "Basic Regulation", hereinafter, "BR"). The Community Plant Variety Rights Office (henceforth, "CPVO", located in Angers, France) provides for administrative services and is the appellate body, playing an essential role as this "sui generis" kind of IP having a great impact on public interests matters as climatic changes; access to improved varieties; safeguard of agricultural production; food safety; environmental protection. These important scopes are present in several of the BR's recitals, and in particular in art. 13.8, which stated the important principle that:

> *"the exercise of the rights conferred by Community plant variety rights may not violate any provisions adopted on the grounds of public morality, public policy or public security, the protection of health and life of humans, animals or plants, the protection of the environment, the protection of industrial or commercial property, or the safeguarding of competition, of trade or of agricultural production".*

As administrative authority, the CPVO is responsible for granting CPVRs. Decisions from the CPVO-Board of Appeal are sujuect to the judicial review of the General Court (hereinafter, "GC") and the Court of Justice of the European Union (hereinafter, "CJEU"). Therefore, the CJEU provides preliminary rulings on the final interpretation of this "new" form of Intellectual Property Rights (hereinafter, "IPRs") and the complex issues thereof.

The CJEU has reviewed cornerstone principles of the EU PVR law and, namely: the interplay between trademarks and varietal denominations[2];[3] the extent of CPVR exhaustion (compared with other EU-wide IPs, namely the Design)[4]; the concept of *"testing and evaluation"* disposals of the variety not causing the loss of novelty according to Art. 10(1) BR and the relationship with the situations laid down Art. 10(2) BR[5]. Other CJEU's judgments are regarded to the scope and limits of breeders' exclusive rights on the basis of the *"cascade protection"* scheme set out in Art. 13(2) and (3) BR[6]. The CJEU decisions have to be blended with the case law of national courts tackling other pivotal topics in the field of PVR[7], as the definition of the "essentially derived variety" and its practicable consequence/management.

This article is going to review some of the most interesting judgments with regards to critical keynote issues in PVR. Firstly, Firstly, we will discuss the recent case laws dealing with the sui generis novelty regime in PVR system, the "purpose of exploitation" rule, and further exceptions. Secondly, the interplay between varietal denominations (an important element of PVRs) and Trademarks will also be pointed out, indicating their different "essential functions" and treatment. The boundaries of breeders' exclusive rights as per the "cascade protection", as reaffirmed by the CJEU in the "Nadorcott" judgment, will be also discussed together with other important considerations coming from this important decision. Finally, this work will present the recent developments of the complex (legal) concept of the Essentially Derived Varieties.

1.2 THE CONCEPT OF "TESTING AND EVALUATION" DISPOSALS AND THE SITUATIONS COVERED BY ART. 10(2) BR.

Novelty regime in PVRs substantially differs from novelty in patents, as it is constructed on the "commercial novelty" criterion. Indeed, in case of PVRs, it is effective exploitation of the variety (either its varietal constituents or the harvested material, as clarified from 2009 UPOV Explanatory Notes)[8] and not the "disclosure" of the teaching embodied the invention, to cause the loss of novelty.

By setting the novelty requirement, Art. 6 of UPOV[9] has introduced the subsequent requirement that, to be detrimental of the validity of the PVR, disposal of the variety to third parties must occur with the consent of the breeder for the "purpose of exploitation"[10].

This other requirement was intended to simplify the assessment of the novelty-destructive disposals, as the simple "offer for sale or marketing" of the variety was considered a novelty destructive activity in earlier versions. Art. 6(1)(b)(ii) of UPOV 1978 expressly excluded the *trials* of the variety *not involving* sale or disposal to others for exploitation purposes of the variety.

In the BR, the general rule (purpose of exploitation) is confirmed by Art. 10(1) BR, while (2) paragraph foresees various circumstances under which the disposals will not be deemed for exploitation purpose without therefore involving the loss of novelty.

The interpretation of Art. 10(1) and especially (2) BR revealed difficult over the time, leading the 2012-2015 CPVO Ad Hoc Legal Working Group (LWG)[11] to propose the adoption of new recitals in the BR, as well as new paragraphs in Art. 10 BR. That was to cope with the correct interpretation of the "event" negating novelty (physical transfer or the material or agreement, varying on the different legal traditions in the MS).

An important clarification in the interpretation and assessment of Novelty has been released by UPOV on October 22nd 2009, with the adoption of the current version of the Explanatory Notes (hereinafter, only "EXN") about Novelty[12], containing a positive list of disposals for "testing and evaluation purpose", not causing any loss of novelty.

1 The International Union for the Protection of New Varieties of Plants (hereinafter, "UPOV") has introduced this new form of IP rights in 1961. The Convention was adopted in Paris in 1961 and it was revised in 1972, 1978 and 1991. The European Union joins the last version of the UPOV in 1991.

2 Rose Kordes Monique Case Case T-569/18 , W. Kordes' Söhne Rosenschulen GmbH & Co KG v EUIPO, Judgment of the General Court (Second Chamber) [2019];

3 in this regard, the interpretation of the "essential element" within the scope of Art. 7(1)(m) EUTMR is vital;

4 Kanzi Case C-140/10 - Greenstar-Kanzi Europe v. NV v Jean Hustin and Jo Goossens, Judgment of the Curt (First Chamber) [2011];

5 Case T112/18, Pink Lady America LLC v. CPVO, Judgment of the General Court (Third Chamber), [2019];

6 Nadorcott Case; C-176/18,Club de Variedades Vegetales Protegigas v Adolfo Juan Martinez Sanchis, Judgment of the General Court (Seventh Chamber) [2019];

7 The CPVO has exclusive jurisdiction in case of cancellation/nullity proceedings and counterclaims before a national court in the context of an infringement action. This marks a difference between CPVRs and EUTMs.

8 On October 22nd 2009, UPOV published the current version of the Explanatory Notes on novelty under UPOV Convention;

9 See, footnote n. 1;

10 This further requirement is an introduction of UPOV 1991. Under UPOV 1978, it was sufficient, for the loss of novelty, that the variety had been disposed of or simply offered for sale or marketed by the breeder or with his consent.

11 http://cpvoextranet.cpvo.europa.eu/data/acarea/documents/ACLW2015/1025/REPORT%20Ad%20Hoc%20LWG%20to%20AC.pdf.

12 in particular, section 6 of 2009 UPOV EXN states that : "The following acts may be considered not to result in the loss of novelty:
(i) trials of the variety not involving sale or disposal of to others for purposes of exploitation of the variety (clarified in 1978 Act);
(ii) sale or disposal of to others without the consent of the breeder;
(iii) sale or disposal of to others that forms part of an agreement for the transfer of rights to the successor in title;
(iv) sale or disposal of to others that forms part of an agreement under which a person multiplies propagating material of a variety on behalf of the breeder where that agreement requires that the property in the multiplied material of the variety reverts to the breeder;
(v) sale or disposal of to others that forms part of an agreement under which a person undertakes field tests or laboratory trials, or small-scale processing trials, with a view to evaluating the variety;
(vi) sale or disposal of to others that forms part of the fulfillment of a statutory or administrative obligation, in particular concerning biosafety or the entry of varieties in an official catalogue of varieties admitted to trade;
(vii) sale or disposal of to others of harvested material which is a by-product or a surplus product of the creation of the variety or of the activities referred to in items (iv) to (vi) above, provided that the said material is sold or disposed of without variety identification for the purposes of consumption; and
(viii) disposal of to others for the purposes of displaying the variety at an official, or officially recognized, exhibition"; [https://www.upov.int/meetings/en/doc_details.jsp?meeting_id=17484&doc_id=182651]

In *Cripps Pink*[13], the General Court (hereinafter, "GC") has confirmed the pivotal role of novelty, stating that it is in the public interest that a unlawfully granted variety has to be voided and ruled out[14]. Unlike the technical examination, where the CJEU's review of CPVO BoA decisions dealing with complex technical issues is limited to

> *"manifest errors", in the case of nullity proceedings the CJEU is entitled to conduct a full review of the legality of decisions. This is "if necessary examining whether the Board of Appeal concerned made a correct legal characterisation of the facts of the dispute or whether its appraisal of the facts placed before it was flawed (see judgment of 19 December 2012, Brookfield New Zealand and Elaris v CPVO and Schniga, C534/10 P, EU:C:2012:813, paragraphs 39 to 40 and the case-law cited)".*

The GC had to decide whether the commercial exploitation of the Cripps Pink apple tree variety, flowing in Western Australia several years before the application of the CPVR (the novelty bar date), were to be considered detrimental of novelty or not, as it was caused by an "initial disposal" made in 1985 by the breeder for "testing and evaluation" purpose, according to Art 10 (1) BR.

With regards to the 1985 initial disposals, GC drew the following conclusion. While the breeders' letters accompanying the "first disposals" to Western Australian growers could not themselves to qualify them as *"solely for testing"*, after a global appreciation of the surrounding facts and admitted documentary evidence[15], that had to be the only purpose of 1985 disposals, not causing the loss of novelty according to Art 10(1) BR.

The GC pointed out that, without other evidence, Art. 10(2)[16] was not applicable to the further sales occurring in Western Australia. In more details, as the GC pointed out, that article shall be regarded as a *specification* of the circumstances

> *"in which certain legal situations are or are not covered by the concept of disposal for purposes of exploitation of the variety within the meaning of Article 10(1) of the Basic Regulation".*

Therefore, the GC rejected the reading of Art. 10(2) as a definition of the concept and the conditions for "testing and evaluation" disposals, i.e. those *"solely for production, reproduction, multiplication, conditioning or storage"* which would not involve loss of novelty only if i) *"the breeder preserves the exclusive right of disposal of these and other variety constituents'"*, and ii) *"no further disposal is made"*. This interpretation was indeed supported by the comparison of the *"circumstances"* as per Art 10(2) BR and those set out by UPOV 2009 EXN which present a list of disposals and uses of the varieties not involving the loss of novelty (field tests, laboratory trials, evaluation without further multiplication and exploitation of the variety as clarified in the 1978 Act). In the opinion of prominent EU PVR law doctrine, the provision under Art 10(2) constitute indeed an *"exception to or, depending on the interpretation, further elaboration of the main rule given in the first paragraph"*[17]. According to the GC, it is sufficient, to avoid the loss of novelty, that the disposal to a third party being made by the breeder or with his consent without the *"purpose of exploitation of the variety"* according to art 10(1) BR.

GC's interpretation seems therefore to negate the "exception" of "further elaboration" nature of Art. 10(2) BR, with the result that subsequent facts may nevertheless leave intact the novelty, as the intention of the breeder when he disposed of the variety is the only relevant criterion. And that including the avoidance of any preservation of the rights of disposals and the further commercial exploitation.

However, in another case dealing with the interpretation of art 10 BR, the GC held that, for a "testing disposal" of the variety to not cause the loss of novelty, it is necessary meeting that no further sales or disposals of the varieties to third parties for the purpose of exploitation.

In Kiku[18], (cited in the Cripps case) the GC indeed fully referred to the twofold condition for a testing disposal not to cause the loss of novelty according to Art 10 BR, namely (in more details, *"En outre, il y a lieu de rappeler qu'une cession aux fins d'essais sur la variété n'impliquant pas la vente ou la remise à des tiers à des fins d'exploitation de la variété n'est pas destructrice de nouveauté au sens de l'article 10 du règlement no 2100/94"*).

From a point of view, the interpretation of Art 10(2) BR and its systematic position with regards to Art 6 UPOV and UPOV EXN on Novelty is still open to further developments by either the GC and eventually the CJEU. Given the extreme importance of a uniform interpretation of an important and fundamental public-order rule, it was a pity that the CJEU disallowed the appeal brought against GC's Judgment in Cripps Pink[19], especially based on of the different approach adopted in Kiku. That is probably a missed opportunity to treat a matter of extreme significance, with respect to the unity, consistency or development of EU law[20].

1.3 THE ROLE OF NATIONAL COURTS IN THE ASSESSMENT OF CPVR VALIDITY

Unlike the EUTMR[21], Art. 105 BR sets out that *"A national court or other body hearing an action relating to a Community plant variety right shall treat the Community plant variety right as valid"*. This rule has been unanimously considered as reserving the CPVO the competence to assess nullity actions[22]. National courts have jurisdictions in case of infringement. However, by Order of February 26th 2014, the Tribunal of Milan addressed a "nullity exception" filed by Agriseeds SRL against Gautier Semences SaS in case 27229/2012[23]. Gautier filed an injunction order alleging infringement of its exclusive rights on a seeds registered variety and Agriseeds raised an exception for lack of novelty based on various evidence showing commercialization of the seed's variety before the novelty grace period. Even though within the limited and summary scope of the preliminary injunctions pursuant Art 700 of Italian procedural code, the Italian Court, found in favor of Agriseeds for the lack of novelty of the seed variety, hence dismissing the seizures orders and other measures requested by Gautier. The importance of the Milan case is self-evident, as it could open the way for an alternative and potentially concurrent assessment of the EU Plant Breeders' Rights (PBR) Novelty.

1.4 RELATIONSHIP BETWEEN VARIETAL TRADEMARKS (VT) AND PLANT VARIETY DENOMINATIONS (PVD): THE NAME OF THE ROSE.

About denominations, it is interesting to monitor the evolution of CJEU case-law, with regards to the interplay between EUTMs and earlier varietal denominations. A Plant Variety Denomination (hereinafter, "PVD" or "VD") is the name that the breeder chooses when filing a PVR application. The PVD plays a twofold function. Precisely, until the PVR will be validly registered, it will form the object of the exclusive right of the PVR owner, and it will be subject to an obligation to be used in the commercialization of the variety according to Art.17 BR[24]. Upon expiry, instead, the VD will essentially play a public interest function, as it will be the generic name of the variety uniquely identifying the variety in the marketplace. For this reason, as the breeder has the faculty to adopt also a (varietal) trademark to identify its variety[25], Art. 7(1)(m) EUTMR establishes an absolute ground of refusal. Indeed, the applied-for trademark will need not to cause a LoC with earlier (even expired) varieties, as this would hamper the free-use right of the VD[26]. Art. 20 of UPOV 1991 indeed demands that *"no rights in the designation registered as the denomination of the variety shall hamper the free use of the denomination in connection with the variety, even after the expiration of the breeder's right"*.

UPOV[27] and CPVO[28] have released their EXN and Guidelines on varietal denominations and class-31 trademark examination, limiting the adoption of a denomination that is identical or is confusingly similar with another variety of the same or of a "closely related species". Traditionally, EUIPO has always considered this impediment in a strict way, raising objections and rejecting EUTMs application in class 31 when the CPVO variety finder databases showcased existing varieties with the same or a confusingly similar name.

13 Pink Lady America v CPVO, cited;
14 Pink Lady America v CPVO, cited, para 45 and reference to para 52 of Schräder v CPVO, C546/12 P, EU:C:2015:332
15 Pink Lady America v CPVO, cited, para 65;
16 Art 10 (2) BR relates indeed "disposal of variety constituents to an official body for statutory purposes, or to others on the basis of a contractual or other legal relationship solely for production, reproduction, multiplication, conditioning or storage, shall not be deemed to be a disposal to others within the meaning of paragraph 1, provided that the breeder preserves the exclusive right of disposal of these and other variety constituents, and no further disposal is made";
17 European Plant Variety Protection, Würtengerber, Van Der Kooij, Kiewiet, Ekvad, Oxford 2015, par. 3.66 etc.
18 C-444/19, Kiku v CPVO — Sächsisches Landesamt für Umwelt, Landwirtschaft und Geologie (Pinova), T-765/17, paragraph 74:
19 C886/19 P, Pink Lady America v. UCVV, [2020];
20 For an analysis on the effects of the new procedure set forth by Article 170a of the Rules of Procedure of the CJEU, see Antonella Gentile, One year of filtering before the Court of Justice of the European Union, Journal of Intellectual Property Law & Practice, 2020, Vol. 15, No. 10
21 According to Art 124 (d) EUTMR 2017/1001, EU trade mark courts shall have exclusive jurisdiction or counterclaims for revocation or for a declaration of invalidity of the EU trade mark (pursuant to Article 128).
22 This provision underlines the fact that only the Office is competent with regard to the nullification or cancellation of a Community plant variety right. Kiewiet, Plant variety protection in the European Community, WPI, 27 (2005). Pgs 319 (322);
23 Available through the case-law finder at CPVO website;
24 The obligation to display the varietal name in the trade of the varieties (and their harvested material), also plays the essential public order function to permit, from the outset, the identification of the variety with its future generic denomination. This is why a varietal denomination "must be used not only by the breeder but also by any other person who offers for sale or markets reproductive or vegetative propagating material of that variety", European Plant Variety Protection, Würtengerber, Van Der Kooij, Kiewiet, Ekvad, Oxford 2015, par. 6.39.
25 In this sense, it is important to distinguish between "umbrella" trademarks referring to many varieties, and "varietal trademarks" selected to distinguish one particular plant variety, with the exclusion of other genera/species of products traditionally classified under the class-31 of Nice Classification.
26 UPOV and CPVO have released their Explanatory Notes on varietal denominations, allowing the use of similar or identical VDs when they relate varieties of "unrelated botanical species";
27 https://www.upov.int/export/sites/upov/publications/en/pdf/upov_inf_12_3.pdf;
28 https://cpvo.europa.eu/sites/default/files/documents/lex/guidelines/VD_Guidelines_explanatory_note_EN.pdf;

However, on October 15th 2015, in some decisions related to six joined cases dealing with class-31 trademark application[29] (also, upon participation by the CPVO BoA in the oral hearing), the EUIPO consented the registration of the applied-for trademarks when they related varieties of "unrelated species". The EUIPO also allowed the trademark applicant to specify the list of "goods" excluding the varieties already registered, according to the IP Translator case law.

In Kordes', the CJEU had the opportunity to assess the likelihood of confusion between VDs and Trademarks and to provide an interpretation of the "essential element" of the VD according to Art 7(1)(m) EUTMR[30]. "Kordes' Rose Monique" EUTM application has been initially rejected by the EUIPO in reason of the earlier (and expired) "Monique" rose VD. The BoA upheld the Opposition Division decision, finding that the applied-for trademark could have hampered the free usage of the Monique rose variety in the market. However, the GC has refused to automatically attach any "essential element" character to the Monique component of the applied-for trademark, simply because of the correspondence with an earlier (expired) varietal denomination. In the lack of a judicial definition of the "essential element" of a VD, the GC considered the scope of the UPOV legislator was that of preserving the essential function of the varietal denomination, i.e. its free usage to identify the variety. It will be only when the varietal denomination will overlap with the dominant component of the applied-for trademark that such free usage may effectively be hampered, in breach of Art. 7(1)(m) EUTMR.

That was not the case. After the GC applied the "dominant element" criteria in paragraph 32, the result that the concept conveyed by the trademark was only that it referred to one of the various Monique rose varieties sourced from a particular company. And, exactly, that one in this case the Kordes (which will play the trademark "essential function", according to *Tetra Pharm (1997) / EUIPO – Sebapharma (SeboCalm)*, T441/16, not published, par 49 and the case-law cited).

The importance of the Kordes' Judgment is evident, especially considering that most of the trademarks are associated with a specific plant variety. As a result, the existence of earlier varietal denomination will also influence the likelihood of confusion assessment between trademarks and, particularly, the dominant character of their component when they are also part of earlier valid and/or expired VD relating to the same botanical species.

1.5 THE NADORCOTT CASE AND THE SCOPE OF BREEDERS' RIGHTS

In Nadorcott, the Spanish Court was dealing with the provisional protection as per Art. 95 BR in a case where trees of variety already purchased from a public nursery were planted by the grower and the fruits issued thereof were commercialized before the grant of the relevant PBR. The CJEU was required to answer the question referred by the Spanish Court. In short, it was necessary to address whether, before the granting of the plant variety certificate, the reproached acts amounted to an *"unauthorized use"* of the plant varieties according to Art. 13(2) and (3) BR.

These two provisions play a fundamental role in the UPOV systematic legislation, as they organize the limits and scope of protection of breeders' rights on several levels: the so called "cascade protection" system. The first level comprehends those acts requiring the authorization of the breeder, and they are enlisted under Art 13(2). These acts are exclusively related to the "variety constituents", notwithstanding the formulation of said article taking also into account the "harvested material". Indeed, this is clarified in Art 13(3), stating that provisions under Art. 13(2), i.e. acts reserved to the breeder's authorization, will apply to harvested material *"only if this was obtained through the unauthorized use of variety constituents of the protected variety, and unless the holder has had reasonable opportunity to exercise his right in relation to the said variety constituents"*.

The difference is vital as, prior to the grant of the PBR, it would not be technically possible for the breeder to allege infringement of his exclusive rights under Art 94 BR because it is only with the grant of the PVR that such authorization may be sought or even granted.

As a consequence, the breeder will have no valid claim and the fruit will be freely commercialized in the market when it will not be possible to claim/demonstrate that the fruit has been produced from "unauthorized" trees (including the case of trees planted before the grant).

In this sense, Nadorcott Judgment invests indeed major and fundamental aspects of the UPOV legislation, notably the scope and extent of breeders' exclusive rights, and their rationale. Since the first version of UPOV 1961, the scope of breeders' exclusive rights have been limited to the use of the *varietal constituents* for propagating purposes[31]. The word "harvested" has been introduced by UPOV 1991 according to the "cascade protection" system. In particular, it offered the opportunity for the breeders to exercise their exclusive rights also with regards to the harvested material, under specific (restrictively interpreted) conditions set out in Art. 14(2) UPOV 1991, translated by Art. 13(3), to prevent re-importation of fruits/cut flowers from countries where no PVR protection was available.

The Advocate General and the CJEU have interpreted and read systematically the whole PVR legislation, including the UPOV Explanatory Notes and the discussions taking place in the last decades during the UPOV Diplomatic Conferences.

In response to the Spanish Court, the CJEU has considered that the acts of planting (already multiplied) fruit trees and harvesting/selling fruit issued therefrom fall outside the scope of Art. 13(2) BR, which is limited to *production/reproduction* acts (the case related a mandarin tree variety, where fruits may not be used as reproduction material)[32].

Indeed, the Court has considered the "contest" in which Art 13 arises. In particular, under 5, 14 and 20 recitals of that regulation, even though the scheme introduced by the European Union is intended to grant protection to breeders who develop new varieties in order to encourage the breeding and development of new varieties for the public interest, *"such protection must not go beyond what is necessary to encourage such activity, otherwise the protection of public interests such as safeguarding agricultural production and the need to supply the market with material offering specified features, or the main aim of maintaining the incentive for continued breeding of improved varieties may be jeopardized"*. According to a combined reading of Recitals 17 and 18 of that regulation, the agricultural production constitutes a public interest that justifies restricting the exercise of Community plant variety rights. The limitation of breeders' "jus prohibendi" to acts having as their object vegetative propagating material, as defined in art. 13(2), is the pillar of this "cascade protection" system.

The result is the following. The planting of a fruit tree which already formed the object of vegetative reproduction has to be considered as falling under art. 13(3), as its purpose is to harvest and selling fruits in the market, and as such, it may only be "authorized"/"prohibited" after the relevant PVR title has been granted.[33]

The coherence of the Nadorcott Judgment and the "cascade protection" system set out by UPOV in 1961 seems to be also confirmed by the fact that Art. 95 qualifies the compensation due to the breeder for the use of its variety before the grant with the "reasonable" adjective.

According to prominent EU doctrine[34], such an article establishes a (retroactive) protection meant to be an incentive to make the material of the applied-for variety available prior to the grant of plant variety protection. And, this would be compensating the lack of damage claims and/or injunctions which may only be asserted upon the grant, with possible inhibitory effect on the willingness of breeders to make available to third parties material of the variety. This would indeed go against the purpose of Art 95 BR[35]. Further to Nadorcott Judgment, several orders have been issued by EU Courts dismissing the injunctions (and the requests to uproot entire plantings) filed by several table-grape variety owners claiming infringement of their PVR with regards to plantings occurred before the grant.

1.6 ESSENTIALLY DERIVED VARIETIES

EDV is a critical (legal) concept introduced by UPOV 1991 and transposed by Art. 13(5)(a) and (6) BR, giving effect to the recital stating (emphasis added) *"[Whereas] in certain cases where the new variety, although distinct, is essentially derived from the initial variety, a certain form of dependency from the holder of the latter one should be created"*.

Since then, the concrete application of the above concept has been extremely difficult, as it seems to counter the fundamental UPOV principle of the breeders' exception, i.e. that no PVR may never restrict/impede the breeding, discovering and developing other varieties starting, as per art. 15(c) BR.

[29] https://cpvo.europa.eu/en/news-and-events/news/denominations-plant-varieties-and-absolute-grounds-refusal-ctm-applications;

[30] It shall be pointed out that, before the introduction of this new ground of refusal, EUIPO was entitled to raise objections on the basis of the descriptiveness and lack of distinctive character principles set forth under articles 7(1)(b) and (c) of earlier EUTMR versions.

[31] Prof. Jay Sanderson, Towards a (Limited) Cascading Right, (2011) 34(3) UNSW Law Journal 1104

[32] The 2013 UPOV Explanatory Notes on acts in respect of harvested material already clarified that "unauthorized use" refers "to the acts in respect of the propagating material that require the authorization of the holder of the breeder's right in the territory concerned (Article 14(1) of the 1991 Act), but where such authorization was not obtained. Thus, unauthorized acts can only occur in the territory of the member of the Union where a breeder's right has been granted and is in force".

[33] It is indeed also necessary that the breeder had no any earlier "reasonable opportunity to exercise his right in relation to the said variety constituents", with an evident link with the limited "exhaustion" rule set for by art 16 BR. See point 31, "In particular, it is clear from the provisions of Article 16 of Regulation No 2100/94 relating to the exhaustion of the protection afforded by the Community plant variety right, that such protection extends to acts concerning material of the protected variety that has been disposed of to third parties by the right holder or with his or her consent only where those acts involve, inter alia, further propagation of the variety in question that was not authorised by the right holder".

[34] European Plant Variety Protection, Würtenger-ber, Van Der Kooij, Kiewiet, Ekvad, Oxford 2015, par. 7.44 etc.

[35] Art 94 (full protection) allows the breeder to "enjoin such infringement or to pay reasonable compensation or both";

In the EU system, if the CPVO finds the candidate variety to be sufficiently distinct (also in respect of the Initial Variety), it will grant the full CPVR without taking any position on EDV claims. Absent a joint request by the Initial Variety (IV) and the EDV owner, the assessment and declaration of an EDV is demanded to the EU national courts, according to art 99 BR[36]. The last version of the UPOV (2017) EXN on EDV gave greater relevance to the concept of *"essential characters"* of the derived varieties, with a particular focus on the commercial/market value of the new features[37]. A new draft of EDV EXN is being discussed before UPOV, in order to adjust the possible interpretative issues resulting from international courtrooms where different approaches often led to diverging decisions. In their joint presentation, the major breeder's association stressed the need of safe guidelines to uniformly apply the EDV legal concept, focusing on the need of practicable and affordable solutions on its concrete management[38].

This seems one of the most delicate issues, as there is a need to set it based on the fundamental and specific principles of PBR law, differing from the principle laid down in the patent law.

The core of the UPOV legal system is the need to provide society with better and improved genetic resources embodied in plant varieties. In particular, it is of great importance that the EDV scope is clearly and carefully limited, in order to not interfere with the legitimate use of any registered variety (or even varieties) for the purpose of new breeding activity.

Unrestricted access to registered plant varieties is the logical premise consenting to the breeding and further commercialization of improved varieties[39]. The breeders' exception - which should introduce a "principle of independence" in the plant varieties as opposed to the "principle of dependency" in the patent world – is an undisputed cornerstone in UPOV legislation[40].

The reference to the patent system is of the utmost importance and this is also in consideration of the recent decision G 3/19 by the EPO Enlarged Board of Appeal. In the mentioned decision, it is said that plants made by technical methods are now patentable (while the general exclusion still applies to plants produced by non-technical processes such as *crossing* and *selection*). As a result, Art. 27(c) of Agreement on a Unified Patent Court (AUPC) contemplates an exception corresponding to biological patent "for the purpose of breeding, or discovering and developing other plant varieties".

This allows free use of patented plant material for breeding, with a license from the patent owner to commercialize new varieties bearing the patented trait. Once the Unitary Patent comes into force, the exemption will take effect in the EU. The EDV will need to be carefully limited and defined, in order not to hamper this general rule. In this sense, the traditional concept is that EDV should be limited to "cosmetic changes" or "me-too" varieties"[41]. Other legislations of the UPVO members also reflect this as, for example, the Australian legislation. In this country, in fact, the authority granting PBRs can assess the EDV claims through opposition proceedings and the successful party will also have a so - called "veto power" for its commercialization.

According to other theory[42], EDV may not amount to a plagiarism/ "mee-too" test, this being demonstrated by the *"clearly distinguishable"* requirement under Art. 7(1) BR in order to register a given candidate variety (together with Uniformity and Stability).

However, it will be important to follow the activity at the UPOV level. In fact, as in the case of a broader definition for the EDV concept, it will also be relevant to clarify its discipline and practical effects[43], so that the work and financial efforts done by the initial breeder may be rewarded and further breeding efforts may be supported.

36 Other UPOV members, notably Australia, adopted a different approach, where the IP Office is entitled to assess the EDV claims within a proceeding similar to EUIPO's EUTMs oppositions: https://www.ipaustralia.gov.au/plant-breeders-rights/understanding-pbr/pbr-detail/essentially-derived-varieties

37 https://www.upov.int/edocs/expndocs/en/upov_exn_edv.pdf.

38 https://www.upov.int/edocs/mdocs/upov/en/wg_edv_2/wg_edv_2_2.pdf;

39 According to UPOV EXN on Breeder's exception: "The exception under Article 15(1)(iii) states that the breeder's right shall not extend to "acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties.". This is a fundamental element of the UPOV system of plant variety protection known as the "breeder's exemption", whereby there are no restrictions on the use of protected varieties for the purpose of breeding new plant varieties", https://www.upov.int/edocs/expndocs/en/upov_exn_exc.pdf;

40 Interestingly, EDV may also form the object of a compulsory license. The grant of PBR compulsory licenses in plant varieties is however subject to strict "public interest" condition, as per the only case decided by the CPVO so far (Decision nr NCL 001, of the 16th of March 2018, https://ipkitten.blogspot.com/2018/04/public-interest-in-plant-variety-rights.html). In contrast, it seems that conditions for the grant of patent compulsory license (and, eventually, also for varieties obtained by technical methods) may be requested for less stringent conditions including the lack of exploitation and the important technical advance of considerable economic importance.

41 The purported scope of EDV was to limit 'plagiarism', 'copycat breeding', 'mimic', 'imitation' or 'cosmetic' varieties, and an unfair free riding on the original plant breeder's time and investment: see Plant Breeder's Rights and Essentially Derived Varieties: Still Searching for Workable Solutions - Charles Lawson, Griffith Law School (2016), p. 1;

42 Dr. Edgar Krieger, CIOPORA's Secretary General, in "EDV: a protection mechanism, not plagiarism prevention", European Seed 1/2021 [https://www.ciopora.org/post/european-seed-1-2021-preview-dr-edgar-krieger-on-edv];

43 In this sense, the seed sector has developed a reliable system to address EDV disputes.

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End-user license agreement on a fruit bag: misleading to consumers?

Perspectives on the border between use & misuse of legitimate powers according to CPVR law

By Marco Lonero Baldassarra, Sabino Sernia

ABSTRACT

Some rumors have recently outspread over a thought-provoking post on social media depicting a sort of "shrink-wrap" license agreement attached to the front of a fruit bag in the United States. As European consumers and professionals, a few questions spontaneously arise: can the above license be deemed as legitimate and, should it be the case, would it be enforceable against final consumers according to Community plant variety laws? Against this background, the paper will preliminary draw comparative views upon US and Community PVR systems, carefully touching upon the exceptions and limitations to the scope of the breeder's rights, the doctrine of exhaustion and the implications it encompasses within the fruit supply chain, in order to finally take a position on whether or not the licensing trends as the above one may be deemed as solidly grounded from a legal standpoint, in accordance with the applicable PVR law at Community level.

1. COMPARATIVE PERSPECTIVES ON THE PROTECTION OF BREEDING INNOVATIONS

IP rights refer to intangible assets that can be embodied in an unlimited number of tangible goods. In this sense, they can usually qualify as both (i) exclusive, insofar as they allow the right holder to prevent any third party from exploitation of the intangible asset, and (ii) absolute, in the same way as classic property rights in physical goods[1]. Accordingly, absent any rights in *rem* or contractual rights of third parties, the right holder should be free to exercise full control over the IP asset.

In the context of agricultural inventions, the breeder – the person who bred, or discovered and developed a new varietal improvement – will be allowed to get a *jus excludendi alios* as remuneration for his/her activity. This is achieved by means of either patent or PVR protection, depending on the national legislation system in force, as Article 27(3)(b) of the agreement on *Trade-Related Aspects of Intellectual Property Rights* (TRIPS) gives Member States the duty to provide at least one legal remedy for the protection of plant varieties, i.e., "either by patents or by an effective sui generis system or by any combination thereof"[2]. Accordingly, some of the signatories (such as the United States) have opted for a national patent system as an alternative to the plant variety protection system for plants.

1.1. The International System for Plant Variety Rights Protection

PVR systems are conceptually deemed to be a viable solution to strike a fair balance between the diverging interests of breeders and the public at large. The goal is to foster technological development via the implementation of effective reward strategies in respect to the breeders' efforts in research and development, which may ultimately benefit society with successful achievements in the agricultural field.

The protection of plant varieties is mandatory for members of the World Trade Organization (WTO), which are obliged to implement the TRIPS provisions. Generally, Member States have adopted the acts of the *International Convention for the Protection of New Varieties of Plants* ("UPOV Convention")[3] by way of compliance[4].

The UPOV Convention came into force in 1968 and was revised in 1972, 1978, and 1991. Signatories of the UPOV Convention have implemented the relevant provisions within their national legislation: the United States has adopted the "Plant Variety Protection Act" ("PVPA")[5], while European countries have implemented national plant variety protection laws. In addition to the national PVR systems, the Community Plant Variety Rights (CPVR) system was established by Council Regulation (EC) No. 2100/94 on Community plant variety rights in 1994 (the "Basic Regulation" or "BR").

The UPOV Convention (1991) has managed to create an international *acquis* for plant variety protection. As regards eligibility for PVR protection, the plantvariety must be new[6], distinct[7] (i.e., clearly distinguishable from any other variety whose existence is a matter of common knowledge), uniform[8] (in its relevant characteristics) and stable (in the sense that the relevant characteristics should be genetically fixed and remain unchanged after repeated propagation)[9].

With reference to the scope of PVR protection, the breeder can benefit from an exclusive right to perform and/or authorize any third party to perform a certain set of activities, namely (i) production or reproduction (multiplication), (ii) conditioning for the purpose of propagation, (iii) offering for sale, (iv) selling or other marketing, (v) exporting, (vi) importing, (vii) stocking for any of the above purposes, in respect to the propagating material of the protected variety[10]. In principle, the above rights do not cover the whole of the plant material, but only its reproductive elements, thus excluding other elements, such as the harvested material[11].

However, it has been observed that "in numerous crops of great economic importance (e.g. flowers, fruit and vegetables) the activity of the breeder is aimed, in many cases, at creating and developing new varieties whose added value lies exclusively in the 'harvested material' (final product), which brings advantages in terms of quality, beauty, organoleptic qualities, presentation, conservation, etc., and not in the propagating material." Therefore, in many cases, "the breeder must follow the downstream strategy in order to capture that added value and guarantee the profitability of his investment, by moving closer to the producer, marketer and consumer of the final product as beneficiaries of the advantages generated by the new variety"[12].

Further to the intense debate regarding legislative negotiations in the context of the Diplomatic Conferences and the Working Group Meetings[13] held since the adoption of the UPOV Convention (1968), signatories have finally agreed upon the introduction, within the current version of the UPOV Convention (1991), of the so-called "cascading right" system. This affords the breeder with an additional layer of protection of the harvested material (and, in some circumstances, the products directly deriving from said material) of the protected variety, subject to specific conditions listed within Article 14(2) of the UPOV Convention (1991).

However, it should be noted that breeder's rights are not unlimited, as the UPOV Convention (1991) establishes a set of exceptions and limitations to the breeder's rights.

1 For a jurisprudential application of such a doctrinal view, see Judgment of the Court, 19 September 2013, in case C-661/11 Martin Y Paz Diffusion SA v. David Depuydt, Fabriek van Maroquinerie Gauquie NV, ECLI:EU:C:2013:577, where it was ruled that "Article 5 of First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks, as amended by the Agreement on the European Economic Area of 2 May 1992, precludes a proprietor of trade marks which, in a situation where there has been use shared with a third party, had consented to the use by that third party of signs which are identical to its marks in respect of certain goods in classes for which those marks are registered and which no longer consents to that use, from being deprived of any possibility of asserting the exclusive right conferred upon it by those marks against that third party and of itself exercising that exclusive right in respect of goods which are identical to those of that third party."

2 See "Agreement on Trade-Related Aspects of Intellectual Property Rights" Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197, 1869 U.N.T.S. 299. Article 27(3)(b). Available at: https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm – accessed on 30 April 2021.

3 See UPOV, International Convention for the Protection of New Varieties of Plants, as revised at Geneva on March 19, 1991, available at: https://www.upov.int/edocs/pubdocs/en/upov_pub_221.pdf – accessed on 30 April 2021.

4 See Blakeney M., Patents and Plant Breeding: Implications for Food Security, Amsterdam Law Forum (2011) 3(3), p. 73.

5 See Plant Variety Protection Act of 1970 (PVPA), 7 U.S.C. §§ 2321-2582.

6 See UPOV Convention (1991), Article 6.

7 Ibid., Article 7.

8 Ibid., Article 8.

9 Ibid., Article 9.

10 Ibid., Article 14(1).

11 As seen below, UPOV Convention (1991) has extended the breeder's right to the harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating material of the protected variety, unless the breeder has had reasonable opportunity to exercise his/her right in relation to the said propagating material. It does not, however, define when an opportunity may be considered "reasonable," leading to uncertainties in the application of a fundamental concept within the Convention.

As regards the former, Article 15(1)(i) provides that the breeder's rights shall not extend to acts which are *both* of a private nature *and* for non-commercial purposes: it follows that non-private acts, even when not for profit-making purposes, may be outside the scope of the exception. Similarly, private acts which are carried out for commercial purposes may also be out of the scope set forth in the provision.

Secondly, the use of the protected variety "for experimental purposes" is deemed not to be covered by the breeder's rights, according to Article 15(1)(ii) of the UPOV Convention (1991).

Thirdly, Article 15(1)(iii) refers to "acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5)[14] apply, acts referred to in Article 14(1) to (4) in respect of such other varieties." This is a fundamental concept of the entire UPOV system, commonly known as the "breeder's exemption," allowing farmers to freely exploit protected varieties for the purpose of breeding new plant varieties.

Last but not least, Article 15(2) of the UPOV Convention (1991) provides for an optional exception in respect to certain varieties which may be reproduced through the harvested product[15], according to which "each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)(a)(i) or (ii)." Interestingly, the wording of the Convention expressly refers to the use of the harvested material of the variety in question by the farmer "on their own holdings": thus, it could be argued that the optional exception "may be considered by UPOV Members not to extend to a transfer of the product of the harvest to another farmer for that other farmer to use for propagating purposes"[16].

With reference to the limitations set forth by the UPOV Convention (1991), Article 16 establishes the rule of exhaustion, pursuant to which the breeder's rights shall not extend to "acts concerning any material of the protected variety… …which has been sold or otherwise marketed by the breeder or with his consent in the territory of the Contracting Party concerned… …unless such acts (i) involve further propagation of the variety in question or (ii) involve an export of material of the variety, which enables the propagation of the variety, into a country which does not protect varieties of the plant genus or species to which the variety belongs, except where the exported material is for final consumption purposes." As will be further explained below, the rule is aimed at clarifying, on the one hand, that PVR holders can only exercise their rights "once in each stage of propagation" while ensuring, on the other hand, that "the breeder's right to prohibit further or unauthorized propagation of the variety is never exhausted"[17].

[12] See Villaroel A., Experiences of Breeders: Role of Contracts in the Exercise of Breeder's Rights, in UPOV "Symposium on Contracts relating to Breeder's Rights" Geneva, 2008, p. 2. Available at: https://www.upov.int/edocs/mdocs/upov/en/upov_sym_ge_08/upov_sym_ge_08_5.pdf – accessed on 30 April 2021.

[13] This concern was raised by professional groups such as the "International Community of Breeders of Asexually Reproduced Ornamental and Fruit Plants" ("CIOPORA"), arguing that limiting protection to propagating material was "illusive" for vegetable production because plant breeding was a heterogeneous activity and the destination of the crop was not always known. See, on this topic, Sanderson J., *Towards a (Limited) Cascading Right: What is the Appropriate Scope of Protection for Plant Breeding?*, UNSW Law Journal, (2011) Volume 34(3) p. 1108 referring to UPOV, Actes des Conférences Internationales pour la Protection des Obtentions Végétales 1957–1961, 1972, UPOV Publication No 316 (1972), 92.

[14] I.e., essentially derived varieties, varieties which are not clearly distinguishable from the protected variety and those whose production requires the repeated use of the protected variety.

[15] E.g., grains and cereals.

[16] See WIPO *Introduction to Intellectual Property: Theory and Practice* (2nd ed.) Kluwer Law International (2017) p. 261.

[17] *Ibid.*, p. 262.

[18] See UPOV Convention (1991) Article 19.

[19] See Chiarolla C., *Commodifying Agricultural Biodiversity and Development-Related Issues*, 9 J. World Intell. Prop. 25, (2006), p. 28.

[20] *Ibid.*

[21] Ibid., p. 29.

[22] See US Department of Agriculture (USDA) "Plant Variety Protection – Overview" section, available at: https://www.ams.usda.gov/services/plant-variety-protection – accessed on 30 April 2021.

[23] See "Plant Variety Protection Act " of 1970 (PVPA), 7 U.S.C. sections 2321–2582.

[24] See U.S. "Patents Act" 35 U.S.C. §§ 161 et seq. Available at: https://www.wipo.int/edocs/lexdocs/laws/en/us/us176en.pdf – accessed on 30 April 2021.

[25] US Patent Acts of 1790, 1793, 1836, 1952; "Leahy-Smith America Invents Act" (AIA) of 2011; 35 U.S.C. sections 101, 102, 103 and 112.

[26] US Patent and Trademark Office (USPTO), "General Information About 35 U.S.C. 161 Plant Patents" available at: https://www.uspto.gov/patents/basics/types-patent-applications/general-information-about-35-usc-161 – accessed on 30 April 2021.

[27] 35 U.S.C. § 101.

[28] 35 U.S.C. § 102.

[29] 35 U.S.C. § 103.

[30] 35 U.S.C. § 112(a).

[31] Ibid.

[32] Ibid.

[33] 35 U.S.C. § 112(b).

[34] See, on this topic, Holthuis J., Van der Velden M. (general editors) Plant Variety Rights Versus Plant Patents: Legal Developments and Frictions in a Regional Perspective in Business Law International, Vol. 20 no. 2 (2019) p. 105.

[35] Ibid.

[36] Reference is made to 227 USPQ 443, 447 (Bd Pat App & Int 1985). See also, Bugos G.E. and Kevles D.J., Plants as Intellectual Property: American Practice, Law, And Policy in World Context (California Institute of Technology, Pasadena 1991).

[37] See Holthuis J., Van der Velden M. (general editors) Plant Variety Rights Versus Plant Patents: Legal Developments and Frictions in a Regional Perspective, p. 105.

Lastly, as regards the duration of the breeder's right, the UPOV Convention (1991) provides for a minimum period of 20 years from the date of the granting of the PVR protection. In case of trees and vines, the period shall not be shorter than 25 years[18].

1.2. Critical gaps between PVR Protection and Plant Patent Protection

As far as the relationship between PVRs and patents is concerned, it should be noted that the requirements for PVR protection are less strict than those of any patent system, because "the criteria of distinctness, uniformity and stability… …can provide more flexibilities than requirements for patentability"[19]. Therefore, in principle, "plant varieties, including plants growing in the wild, may be eligible for protection simply if they are distinct from earlier known species"[20].

It follows that PVR protection is "softened" as compared with patent protection. Breeders may benefit from one or the other, either as a stand-alone protection or in combination with other protection schemes, depending on the availability within the national legislative system of the territory concerned.

Furthermore, the requirements for patent protection relate to the "solution to a technical problem," as the invention must be new, involve an inventive step and must have an industrial application. On the other hand, the requirements for PVR protection are less demanding and easier to determine. This results in a relatively narrow scope of protection that, aside from the further amendments to the UPOV Convention (1991), does not generally extend to all products (particularly not those for consumption and/or use), but only to the propagating material of the protected variety.

With reference to scope, the protection afforded by the patent system is broader than the standard set of rights obtained via PVR legislation, due to the important exceptions and limitations in the latter system.

Since the objective of PVR systems is to afford legal protection in respect of the propagating material of the variety, breeders' rights do not cover "technical processes for the production of those varieties"[21]. In other words, breeders cannot obtain exclusive rights over particular breeding methods through PVR systems, whereas they can, in principle, apply for patent protection for such a process under national patent laws.

Thus, if national legislation provides for a patent protection system for plants, a breeder could potentially achieve patent protection for both the plant variety and the breeding process involved.

Lastly, patent protection systems allow an applicant to obtain legal protection for both a plant and the genetic material expressed by that plant: the former will qualify as a plant patent, while the latter will qualify as a plantrelated invention. Under PVR systems, plant genetic materials remain unprotected and available to the public for further research and development, in accordance with the "breeder's exemption," whose Community application can be found within Article 15 of the Basic Regulation (the so-called "farmers' privilege").

1.3. Plant Variety Protection Schemes in the United States

In the USA, three types of protection can be obtained for new plant varieties by breeders[22]:

- Plant Variety Protection – for seeds, tubers, and asexually propagated plants[23];
- Plant Patents – for asexually propagated plants except edible tubers[24];
- Utility Patents – for genes, traits, methods, plant parts, or varieties[25].

A plant patent is granted by the United States Patents and Trademarks Office (USPTO) to an inventor. The relevant title, which is valid for 20 years from the filing date of the application, allows the patent holder to exclude any third party from asexually reproducing the plant and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any part thereof, into the United States. This protection is limited to a plant in its ordinary meaning, which is described in the relevant regulation[26].

The requirements for patent protection are different from the conditions established for the PVR system. For a patent to be granted, the variety applied for must comply with the following criteria: 1) utility[27], 2) novelty[28], 3) non-obviousness or inventive step[29], 4) enablement or sufficiency of disclosure[30], 5) written description[31], 6) best mode[32], and 7) specification[33].

The patentability requirements for a plant variety are the same as those for usual patents (so-called utility patents); however, the application of these requirements is less stringent for plant patents.

The USPTO is the office authorized to issue a utility patent: this can cover any plant or plant part, as long as the invention satisfies the basic criteria of patentability under US law (*i.e.*, the invention is unique, useful, non-obvious, and not a product or law of nature). Utility patents can also protect plant traits embodied in a group of plants[34].

The utility patent (which has a 20-year term from the filing date of the application) allows the patent holder to prevent others from making, using, selling, offering for sale, and importing or exporting the patented invention within the relevant territory (*i.e.*, USA). There are no exemptions to these prohibitions relevant to commercial agriculture. Once claims in the application have been granted, the biological deposit becomes publicly available[35].

Since the "*Ex parte* Hibberd" ruling[36], thousands of utility patents have been issued on plants – there is no limitation on the type of plant patented. One important implication is that patent holders can prevent others from using the patented variety for breeding[37].

Plant Variety Protection (PVP) certificates are issued by the Plant Variety Protection Office (PVPO) of the US Department of Agriculture (USDA) under the Plant Variety Protection Act (PVPA), 7 U.S.C. sections 2321–2582. A PVP certificate may be issued on a plant variety that can be sexually propagated, or is tuberous, if it satisfies the criteria of being new[38], distinct [39], uniform[40], and stable[41]. The PVP certificate covers only one plant variety – not a group of plants that share a common trait – and in this sense is more similar to a plant patent than a utility patent[42].

The certificate (which is generally valid for 20 years from the date of issue or for 25 years for vines and trees) grants the holder the right to prohibit others from selling, offering for sale, reproducing, importing, exporting, or using the plant in commercial production. The protection provided is primarily against unauthorized commercial use of the variety[43].

An important feature of PVP is the research exemption[44], pursuant to which the use and reproduction of a protected variety "for plant breeding" or "other bona fide research" shall not constitute an infringement. These acts, as well as private or non-commercial uses[45], are not considered infringements of the PVPA.

Furthermore, the PVR owner must also allow limited seed saving "by authority of the owner of the variety for seeding purposes," as well as subsequent use of such seeds "in the production of a crop for use on the farm of the person, or for sale as provided in this section"[46].

In light of the above, PVR protection seems to be less restrictive than utility or plant patent protection, allowing certain uses of the protected variety in research and agricultural contexts.

From a strategic point of view, it has been argued that utility patent and plant patent protection may partially overlap, insofar as they grant the same rights to a given variety and have the same lifespan. The key difference lies in the scope of the claims. In particular, the plant patent covers "only the entire plant of the new variety as described in the application" while the utility patent allows coverage "beyond a single plant variety," although the process of getting a plant patent is typically less complicated and less costly than that for a utility patent[47].

An advantage of obtaining a utility patent on plant traits is that the coverage can be broad. Multiple varieties with the same trait can be covered in a single application, provided that those varieties are not covered by any other source of IP. Further, the patent can also cover new varieties independently developed from the plant and bearing the same trait.

1.4. The Community Plant Variety Protection System

The European Union formally joined the UPOV system in 2005. However, as early as 1994, the European Union had adopted the Basic Regulation, establishing the Community plant variety rights (CPVR) system, along with the relevant implementing Regulation[48] as well as the Regulation concerning the so-called "agricultural exemption"[49]. As in the case of Community trademarks and designs, the BR allows for an IP right with unitary effects throughout the entire European Union.

As regards the protectable subject matter, CPVRs are granted in respect to "[v]arieties of all botanical genera and species, including, *inter alia*, hybrids between genera or species"[50], where the expression "variety" is commonly intended as "a plant grouping within a single botanical taxon of the lowest known rank, which ... can be: (i) defined by the expression of the characteristics that results from a given genotype or combination of genotypes, (ii) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and (iii) considered as a unit with regard to its suitability for being propa-gated unchanged." In line with the provisions within the UPOV Convention (1991), a variety must be new, distinct, uniform, and stable in order to be eligible for CPVR protection[51] .

As far as the novelty requirement is concerned, the BR provides that "A variety shall be deemed to be new if, at the date of application... ...variety constituents or harvested material of the variety have not been sold or otherwise disposed of to others, by or with the consent of the breeder... ...for purposes of exploitation of the variety: (a) earlier than one year before the above-mentioned date, within the territory of the Community; (b) earlier than four years or, in the case of trees or of vines, earlier than six years before the said date, outside the territory of the Community"[52].

The novelty rule provides for a "grace period" in respect to acts of sale and/or disposal of the variety prior to the relevant application date. Moreover, the concept of "disclosure" of the variety applied for is limited to acts performed by the breeder or with his/her consent (whereas for patents, acts of disclosure performed by third parties are enforceable also against the patent holder, provided that such acts are due to, or in consequence of, an evident abuse in relation to the applicant or his/her legal predecessor and the patent application is duly filed within six months from the disclosure event)[53].

The variety applied for shall be deemed to be distinct "if it is clearly distinguishable by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety whose existence is a matter of common knowledge" on the date of application[54]. Here, the concept of "common knowledge" entails any variety that is comprised within the "state of the art" at the time of the CPVR application, if (i) it was the object of a PVR or entered in an official register of plant varieties, in the Community or any State, or in any intergovernmental organization with relevant competence, or (ii) an application for the granting of a PVR for said variety or for its entering in such an official register was filed, provided that the application has since led to such granting or entering.

As previously mentioned, a variety must be "clearly" distinguishable from the prior art: for this reason, the distinctiveness requirement has been conceptually likened, by some scholars, to the "inventive step" within patent law[55]. The distinctiveness requirement is to be assessed through "the expression of the characteristics that results from a particular genotype or combination of genotypes": according to authoritative doctrine, this clarification[56] should lead to denying CPVR protection whenever the genetic distances between the variety applied for and those in the prior art are of only trivial importance[57].

However, this interpretation has been rebutted by other scholars. It has been argued that even minimal genetic differences, if they translate into phenotypic differences or differences in the main features of the plant variety in question, shall be deemed sufficient to meet the distinctiveness requirement[58]. In line with the above argument, UPOV TG/1/3[59] suggests that the distinctness requirement shall be looked at in relation to "the characteristics expressed by the genotype" rather than the genotype *per se*.

Last but not least, CPVR protection is granted for varieties that are sufficiently uniform "in the expression of those characteristics which are included in the examination for distinctness, as well as any others used for the variety description"[60] and stable, in the sense that "the expression of the characteristics which are included in the examination for distinctness as well as any others used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle"[61]. As regards those two requirements, some scholars have linked them to the "industrial applicability" requirement in patent law, insofar as both serve to ensure reproduction of the intellectual creation[62].

In line with the relevant provisions of the UPOV Convention (1991), the BR delivers a set of activities which must be subject to the breeder's prior authorization, namely (i) production or reproduction (multiplication) of the protected material, (ii) conditioning for the purpose of multiplication, (iii) sale or marketing, (iv) exportation from or importation to the territory of the Community, and (v) storage for one of the aforementioned purposes[63].

This notwithstanding, the BR provides for the statutory exceptions[64] set forth by the UPOV Convention (1991), namely (i) acts done "privately and for non-commercial purposes" by farmers who may benefit from the availability of protected new varieties, (ii) acts done for experimental purposes, and (iii) acts done for the purpose of breeding or discovering and developing other varieties (i.e., the "farmers' privilege"). The BR also provides for a general clause concerning limitations to the CPVR[65] as

38 7 U.S.C. § 2402(1).
39 7 U.S.C. § 2402(2).
40 7 U.S.C. § 2402(3).
41 7 U.S.C. § 2402(4).
42 See Holthuis J., Van der Velden M. (general editors) Plant Variety Rights Versus Plant Patents: Legal Developments and Frictions in a Regional Perspective, p. 106.
43 Ibid.
44 7 U.S.C. § 2544.
45 7 U.S.C. § 2541(e).
46 Reference is made to the "right to save seed" and the "crop exemption" under 7 U.S.C. § 2543.
47 See Holthuis J., Van der Velden M. (general editors) Plant Variety Rights Versus Plant Patents: Legal Developments and Frictions in a Regional Perspective, p. 108.
48 See Commission Regulation (EC) No. 874/2009 of 17 September 2009 establishing implementing rules for the application of Council Regulation (EC) No. 2100/94 as regards proceedings before the Community Plant Variety Office.
49 See Commission Regulation (EC) No. 1768/95 of 24 July 1995 implementing rules on the agricultural exemption provided for in Article 14(3) of Council Regulation (EC) No. 2100/94 on Community plant variety rights.
50 See Article 5(1) BR.
51 Ibid., Article 6.
52 Ibid., Article 10(1).
53 See European Patent Office (EPO), European Patent Convention, 17th edition/November 2020 Article 55 available at: https://documents.epo.org/projects/babylon/eponet.nsf/0/B415FE40DAEEEC60C-125864600479CB3/$File/EPC_17th_edition_2020_en.pdf – accessed on 30 April 2021.
54 See Article 7 BR.
55 See Floridia G., Il riassetto della proprietà industriale, Milano, 2005, p. 423; Mayr C., La disciplina delle nuove varietà vegetali, Le nuove leggi civ. comm., 2000, 847 e ss., p. 860.
56 Introduced by the UPOV Convention (1991), probably to take into account the advent of new breeding techniques based on genetic engineering processes: see Mayr C., Commento al Reg. CE n. 2100/94, Riv. dir. ind., 1995 (VI) and Borrini S., La Nuova Disciplina delle Varietà Vegetali, Il dir. ind., 1999, 16 et seq.
57 See De Benedetti J. - Borrini S., Commento al reg. CE n. 94/2100, Il dir. ind., 1994, 1173, and Ghidini G. - De Benedetti J., Codice della Proprietà Industriale, Milano, 2006, p. 267.
58 See Morri F., La Privativa Varietale Comunitaria, Riv. Dir. Ind., fasc. 1, 2011, p. 19.
59 See UPOV, General introduction to the examination of distinctness, uniformity and stability and the development of harmonized descriptions of new varieties of plants, Geneva, 19 April 2002, available at: https://www.upov.int/edocs/mdocs/upov/en/caj_ag_10_5/tg_1_3.pdf – accessed on 30 April 2021.
60 Article 8 BR.
61 Article 9 BR.
62 See Dragotti G., Commento agli artt. 100 e ss. c.p.i., in Scuffi-Franzosi-Fittante, "Il Codice della Proprietà Industriale" Padova, 2005, p. 471, and Floridia G., Il riassetto della proprietà industriale, Milano, 2005, p. 425.
63 Article 13(2) BR.
64 Article 15 BR.
65 Article 13(8) BR.

well as the exhaustion rule[66], pursuant to which the disposal of "any material" of the protected variety, performed by the breeder or with his/her consent, throughout the territory of the Community, will lead to CPVR exhaustion in relation to that material.

Lastly, it seems worthwhile to underline that CPVRs are afforded in respect to living material that is capable of reproducing itself and generating new products. In light of this specificity, in order to establish whether or not the CPVR is exhausted when dealing with varieties whose harvested material may also serve as propagating material, reference must be made to the actual destination of the material in question. If it is intended for final consumption, the CPVR holder will be unable to oppose the subsequent marketing thereof, whereas he/she can do so if the acts of disposal are intended for further propagation of the protected variety[67].

2. THE DOCTRINE OF EXHAUSTION IN PLANT VARIETY RIGHTS

The doctrine of exhaustion (also known as the "first sale doctrine" in common law jurisdictions) represents a key concept in IP law. The application of this doctrine implies that, further to the first act of disposal of an individual good by the title holder or with his/her consent, the IP rights will generally be deemed "exhausted" (*i.e.*, there will be no more rights in favor of the title holder).

Here, it is important to remember that the exclusive rights of the IP owner refer to the exploitation of the intangible good, not the physical item incorporating it: as outlined by respected scholars, the exhaustion of the right "does not apply to the patented object as an abstract category, family or group, but concerns only the specific object, individually and concretely sold"[68].

That being said, the exhaustion rule in relation to PVRs aims at ensuring that the breeder can exercise his/her exclusive rights and be remunerated only in the first propagating stage. On the other hand, PVR exhaustion guarantees the breeder's right, under certain conditions, to prevent further or unauthorized propagation of the protected variety in question[69].

The right to prohibit further propagation is required for an adaptation of the exhaustion rule from the patent law paradigm. In fact, under PVR, problems may arise in case of harvested material which is nonetheless capable of propagating the protected variety.

The above issue has been addressed at the Community level, *inter alia* under the Biotechnology Directive[70], whose Article 10 expressly provides that patent protection shall not extend "to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication."

Indeed, the exhaustion doctrine in patent law "protects the purchaser from interference in the use of the purchased patented item and in its disposition or sale"[71], whereas in plant variety protection it is necessary to take into consideration that the protected organisms are often able to duplicate themselves. Therefore, a limited interference might be allowed, to protect the PVR holder.

Article 16(1) of the UPOV Convention (1991) provides for a specific provision concerning exhaustion, according to which the breeder's right shall not extend to acts concerning "any material of the protected variety… …which has been sold or otherwise marketed by the breeder or with his consent in the territory of the Contracting Party concerned, or any material derived from the said material, unless such acts (i) involve further propagation of the variety in question or (ii) involve an export of material of the variety, which enables the propagation of the variety, into a country which does not protect varieties of the plant genus or species to which the variety belongs, except where the exported material is for final consumption purposes."

It is interesting to note that the subsequent paragraph (2), clarifying the meaning of the word "material" within the above provision, refers to "propagating material," "harvested material," and "products obtained directly therefrom." It follows that, no matter how the protected variety was actually put on the market, use of any material involving further propagation will lead to PVR exhaustion.

However, a problem arises in connection to the wording "unless such acts (i) involve further propagation of the variety in question." In this respect, some scholars have argued that "further propagation is closely linked to the acts requiring authorization by the breeder." This would mean that "[t]he sale itself does not involve propagation. The breeder can only sue the buyer propagating (production of propagating material) or cultivating (production of harvested material) the material"[72].

With reference to the corresponding provisions enclosed within CPVR law, it should first be observed that the 14th recital in the preamble to the BR states the following: "Whereas, since the effect of a Community plant variety right should be uniform throughout the Community, commercial transactions subject to the holder's agreement must be precisely delimited; whereas the scope of protection should be extended, compared with most national systems, to certain material of the variety to take account of trade via countries outside the Community without protection; whereas, however, the introduction of the principle of exhaustion of rights must ensure that the protection is not excessive."

Against this background, Article 16 BR[73] provides that "the Community plant variety right shall not extend to acts concerning any material of the protected variety, or of a variety covered by the provisions of Article 13(5), which has been disposed of to others by the holder or with his consent, in any part of the Community, or any material derived from the said material, unless such acts: (a) involve further propagation of the variety in question, except where such propagation was intended when the material was disposed of[74]; or (b) involve an export of variety constituents into a third country which does not protect varieties of the plant genus or species to which the variety belongs, except where the exported materials is for final consumption purposes."

In other words, if the CPVR holder or his/her licensee has sold or otherwise disposed of "any material" of the protected variety to third parties within the territory of the European Union, CPVRs will be exhausted in respect to that material: the breeder will not be allowed to prevent any third parties from offering for sale and/or selling that material to others, nor from stocking it for any of the listed purposes[75]. In addition, the above wording suggests that if variety constituents of the protected variety are sold by the CPVR holder or with his/her consent, the purchaser will be allowed to sell the harvested material resulting from those variety constituents.

As previously touched upon, the exhaustion rule within the BR is subject to a number of exceptions. In particular, as a result of the first exception under (a), the CPVR holder will always be entitled to prohibit the propagation of the variety. However, Article 16 BR contains a "counter-limitation" to the exception, in case further propagation was intended at the time of the disposal of the material, e.g., in case of a disposal to a licensee by reason of a contractual exploitation right[76]; in such a case, the act of disposal will be considered as leading to CPVR exhaustion[77].

In this respect, relevant case-law of the CJEU[78] has ruled that "the holder or the person enjoying the right of exploitation may bring an action for infringement against a third party which has obtained material through another person enjoying the right of exploitation who has contravened the conditions or limitations set out in the licensing contract that that other person concluded at an earlier stage with the holder to the extent that the conditions or limitations in question relate directly to the essential features of the Community plant variety right concerned. It is for the referring court to make that assessment." Additionally, the Court observed that "[i]f the referring court were to establish that the protected material was disposed of by the person enjoying the right of exploitation in breach of a condition or limitation in the licensing contract relating directly to the essential features of the Community plant variety right, it would have to be concluded that that disposal of the material, by the person enjoying the right of exploitation to a third party, was effected without the holder's consent, so that the latter's right is not exhausted"[79].

66 Article 16 BR.

67 See Morri F., La Privativa Varietale Comunitaria, p. 6.

68 See Germinario C., A Comparative Look at Bowman vs. Monsanto in the European Context, World Intellectual Property Report, 19 June 2013.

69 The role of the exhaustion doctrine has been addressed by the Supreme Court of the United States in BOWMAN V. MONSANTO CO. ET AL. No. 11–796. In this patent infringement case, which occurred in 2013 and was filed by Monsanto, the Court stated that a purchaser of a patented crop might resell the patented material, consume it him-/herself or use it to feed his/her animals, subject to specific limitations. In particular, it has been held that, even if the patented material is naturally able to replicate itself, the purchaser does not have the right to use such copies without the patent holder's permission. In case an unauthorized replication occurs, the breeder's right is deemed not to be exhausted. For further insights into this ruling, see: Blakeney M., 2016, Agricultural Innovation: Patenting and Plant Variety Rights Protection, in Steier G. and Patel K. (eds.), "International Food Law and Policy, Springer International Publishing" pp. 149- 150. See also: Lai J., 2014, The Exhaustion Doctrine and Genetic Use Restriction Technologies: A Look at Bowman v Monsanto, The Journal of World Intellectual Property, 17, 5-6.

70 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

71 Chamber S., Exhaustion Doctrine in Biotechnology, IDEA: The Journal of Law and Technology (1995) p. 35.

72 See Zech, Herbert, Analysis of Court Decisions on Propagating Material and Harvested Material: Switzerland and European Union, (October 24, 2016) p. 6. Proceedings of the UPOV, Seminar on Propagating and Harvested Material in the Context of the UPOV Convention (Geneva, Switzerland), held on October 24, 2016, Available at SSRN: https://ssrn.com/abstract=2964527 or http://dx.doi.org/10.2139/ssrn.2964527 – accessed on 30 April 2021.

73 Implementing the provision of Article 16 UPOV Convention (1991).

74 The additional clarification implies a shift in the burden of proof against the defendant, who is called upon to provide effective evidence of the fact that the act of propagation was intended when the material had been disposed of by the breeder or with his/her consent, cf. Godt C. in: Metzger/Zech, Sortenschutzgesetz, 2016, § 10c SortG point 8.

75 See G. Würtenberger/P. van der Kooij/B. Kiewiet/M. Ekvad, European Union Plant Variety Protection, 2nd ed., Oxford University Press (2016), § 6.92.

76 See Article 27(1) BR.

77 See European Union Plant Variety Protection" 2nd ed. § 6.105.

78 See Judgment of the Court of 20 October 2011, case C-140/10, Greenstar-Kanzi Europe NV v Jean Hustin, Jo Goossens, ECLI:EU:C:2011:677.

79 Ibid., § 43.

However, the CJEU has not delivered any effective guidance on which features are to be deemed as "essential." In the face of this uncertainty, academics in the field have attempted to fulfill the task by qualifying as essential features referring to, *inter alia*, the number of plants to be produced and sold by the licensee, the quality of the plant material and geographical limitations, while excluding conditions concerning the licensee's internal administration, the policing of the territory involved in the license agreement, and the settlement of disputes[80].

As regards the second exception provided for within Article 16(b) BR, it should be observed that such provision has been introduced in order to protect the CPVR holder in case plant material of the protected variety is used for further propagation in a third country where the variety in question does not enjoy any protection and harvested material obtained therefrom is subsequently exported back into the European Union[81]. This could have a serious economic impact on the CPVR holder.

When the above provision has been read in conjunction with Article 13(3) BR, regulating the scope of the breeder's rights in respect of the harvested material "only if this was obtained through the unauthorized use of variety constituents of the protected variety, and unless the holder has had reasonable opportunity to exercise his right in relation to the said variety constituents," it has been argued that if plant material of a protected variety has been propagated illicitly, and the CPVR holder is only informed about the subsequent marketing of harvested material derived therefrom, he/she would not have had a "reasonable opportunity" to exercise his/her exclusive rights in relation to the variety constituents at an earlier stage[82].

Hence, it is clear that protection of the "harvested material" and products obtained from protected plant varieties will apply only in limited circumstances. The rationale behind the current set of CPVR provisions is for breeders to exercise their rights primarily over the "propagating material" of protected varieties. It is also clear that the assessment of whether or not there has been a "reasonable opportunity" for the breeder to exercise his/her exclusive rights over the plant material at an earlier stage is a judicial matter and, in any case, strictly dependent upon the circumstances in each specific case.

This notwithstanding, the exception under Article 16(b) BR is further neutralized by the provision of the "counter-limitation" pursuant to which exhaustion still applies when the exported material is intended "for final consumption purposes."

In this sense, a doctrinal argument has been raised according to which the above ruling would leave exhaustion effective only "when the material is used fraudulently for propagation in the third country… …The problem could only be solved if the actual use would be taken to change the 'purposes' retroactively. However, taking the actual use into account seems only admissible where the use was already intelligible or tacitly agreed at the time of sale. The actual use can only be taken as an interpretative aid. Therefore, the legal gap cannot be remediated by interpretation"[83].

The provision on CPVR exhaustion refers to "variety constituents" rather than "propagating material." However, most commentators agree that the two expressions should be deemed to be interchangeable[84]. Arguments supporting this position can be found within Article 13(3) BR concerning "harvested material," as well as in the wording of Article 13(2) BR, which expressly differentiates between "variety constituents" and "harvested material." Accordingly, many academics use a definition of "propagating material" which contains at least a reference to either the "destination" or the "actual use" of the material for further propagation.

If this interpretation was to prevail, the additional criteria of the "intended purpose for further reproduction" would be deemed mandatory, while being conceived as a subjective element which must be objectively noticeable at the time of further propagation, allowing the conclusion that "only material which is intended by the buyer (intelligibly for the seller) to be used for cultivation or propagation is to be subsumed as variety constituents"[85] and, if this requirement were not fulfilled, the plant material in question would instead be deemed to be harvested material[86].

[80] See European Union Plant Variety Protection, 2nd ed. § 6.105.

[81] See European Union Plant Variety Protection, 2nd ed. § 6.16.

[82] Ibid., § 6.17.

[83] See Analysis of court decisions on propagating material and harvested material: Switzerland and European Union, Zech H., p. 6.

[84] See European Union Plant Variety Protection 2nd ed. § 6.11; Sabellek A. in: Metzger/Zech, Sortenschutzgesetz, 2016, § 2 SortG point 40; Godt C. in: Metzger/Zech, Sortenschutzgesetz, 2016, p. 10 SortG pt. no. 36.

[85] See Analysis of court decisions on propagating material and harvested material: Switzerland and European Union, Zech H., p. 5.

[86] See Von Gierke K./Trauernicht in: Metzger/Zech (eds.), Sortenschutzrecht, 2015, p. 37 SortG points 23 et seq.

[87] Grace J., Experiences Of Breeders: Role of Contracts in the Exercise of Breeders Rights, in UPOV "Symposium on Contracts in Relation to Plant Breeders' Rights" Geneva, 2008, available at: https://www.upov.int/edocs/mdocs/upov/en/upov_sym_ge_08/upov_sym_ge_08_6.pdf – accessed on 30 April 2021.

[88] See Use of Proprietary Parental Lines of Hybrids, ISF Position Paper, Copenhagen, May 2006.

[89] See Judgment of the Court, 3 July 2012 in case C-128/11, UsedSoft Gmbh v Oracle International Corporation, ECLI:EU:C:2012:407.

[90] Ibid., § 42.

[91] Reference is made to Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs.

[92] See Judgment of the Court, 3 July 2012 in case C-128/11, § 44.

[93] Ibid., § 47.

3. PERSPECTIVES ON THE APPLICATION OF THE EXHAUSTION DOCTRINE IN CASE OF DISPOSAL OF INTANGIBLE GOODS

In the case at issue within the present paper, the right holder seems to (i) qualify the contractual relationship as a license agreement for certain exclusive rights (namely the right to "use" the harvested material of the variety, which is then eaten and/or perishes within a few hours), (ii) associate said license with the actual sale concluded via the transfer of ownership of the grapes against the payment of the price (rights in rem), consequently (iii) asserting his/her rights over said produce, notwithstanding any application of the exhaustion rule seen above.

A few questions may therefore arise: assuming that the license agreement is validly concluded, why would the PVR holder impose a fee designed to obtain only a remuneration corresponding to the economic value of the material goods, rather than a consideration further including the remuneration for the IP rights? In addition, even assuming that the license is conceived as free of charge, the fact remains that it is not subject to any condition and/or limitation: the license agreement appears to be perpetual, non-exclusive, and worldwide. Would it be valid and/or admissible under CPVR laws?

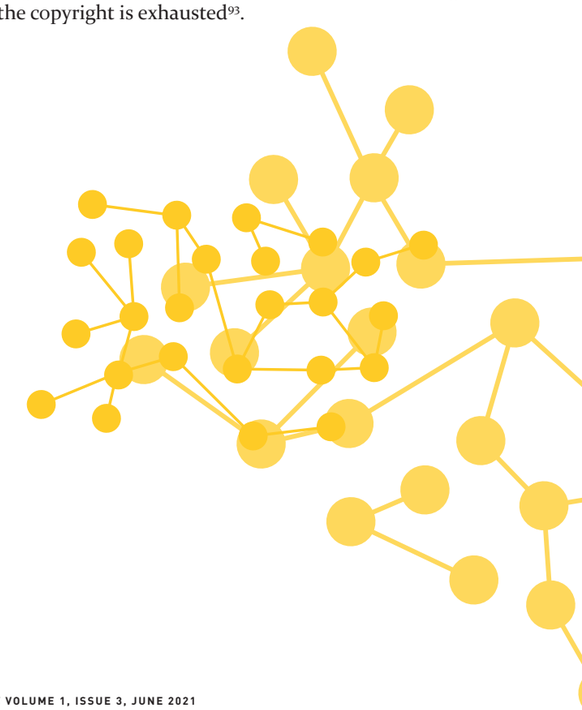
As commonly experienced in the US, through the purchase of a bag of seed, the customer is granted a license over the relevant technology under the "shrink-wrap" language printed thereon. The license in question is usually intended as limited and would not typically allow breeding use, including research or seed production of any seed that may happen to be in the bag. Sometimes, the text on the bag may even restrict the transfer or sale to any third party of the plant material purchased.

As has been observed, the underlying purpose of this is to prevent "the unique genetics in the bag, genetics that may represent twenty years or more of basic research, from being used to create competing products without the permission of and benefit sharing by the owner"[87]. In a 2006 position paper, the International Seed Federation stated that breeders may use any relevant legal mechanisms, including bag tag warnings and/or shrink-wrap agreements, to protect themselves against the unauthorized use of proprietary parental lines for the purposes of breeding[88].

Apparently, there is also an authoritative string of case-law within the US legitimizing the application of such practices within the agricultural sector, which seems quite close to what happens with end-user license agreements (EULAs) for software. However, there is also a strong case against the above trend at the Community level. According to seminal case-law before the CJEU[89], it has been held that (i) the right of distribution of a copy of a computer program is exhausted if the copyright holder who has authorized, even free of charge, the downloading of that copy from the internet onto a data carrier has also conferred, in return for payment of a fee designed to enable him/her to obtain remuneration corresponding to the economic value of the copy of the work of which he/she is the proprietor, a right to use that copy for an unlimited period; and (ii) in the event of the resale of a user license entailing the resale of a copy of a computer program downloaded from the copyright holder's website, that license having originally been granted by that right holder to the first acquirer for an unlimited period in return for payment of a fee designed to enable the right holder to obtain a remuneration corresponding to the economic value of that copy of his/her work, the second acquirer of the license, as well as any subsequent acquirer thereof, will be able to rely on the exhaustion of the distribution right, and hence be regarded as a lawful acquirer of a copy of the computer program and benefit from the right of reproduction.

In the CJEU's line of reasoning, according to a "commonly accepted" definition, a "sale" would qualify as "an agreement by which a person, in return for payment, transfers to another person his rights of ownership in an item of tangible or intangible property belonging to him"[90] . That being said, the CJEU has observed that the commercial transaction which, in accordance with Article 4(2) of the Software Directive[91], gives rise to the exhaustion of a distribution right in respect to a copy of a computer program "must involve a transfer of the right of ownership in that copy." Accordingly, "the downloading of a copy of a computer program and the conclusion of a user license agreement for that copy form an indivisible whole"[92]. In support of this position, the CJEU further held that "downloading a copy of a computer program is pointless if the copy cannot be used by its possessor." Therefore, those two operations must be considered as a whole, in order to be clearly understood from a legal perspective.

In light of the foregoing, the CJEU concluded that "the transfer by the copyright holder to a customer of a copy of a computer program, accompanied by the conclusion between the same parties of a user license agreement, constitutes a 'first sale … of a copy of a program' within the meaning of Article 4(2)" of the Software Directive, meaning that the copyright is exhausted[93].



Simply put, the CJEU did not limit itself to finding that a property right in an intangible asset was possible, but also assumed that such a property right could be transferred. In particular, it was pointed out that if the term "sale" were not given "a broad interpretation as encompassing all forms of product marketing characterized by the grant of a right to use a copy of a computer program, for an unlimited period, in return for payment of a fee designed to enable the copyright holder to obtain a remuneration corresponding to the economic value of the copy of the work of which he is the proprietor, the effectiveness of that provision would be undermined, since suppliers would merely have to call the contract a 'license' rather than a 'sale' in order to circumvent the rule of exhaustion and divest it of all scope"[94].

Thus, as the distribution right is exhausted against the payment of a fee, any subsequent acquirer of the software license would have to be regarded as a lawful acquirer of a copy of a computer program and could subsequently benefit from the right of reproduction.

The analogical application of the aforementioned concepts may have far-reaching consequences in a situation such as that described in this paper:

- The commercial transaction leading to CPVR exhaustion in respect to plant material (i.e., the grapes) would involve the transfer of ownership of that good in favor of the purchaser.
- The material transfer of the goods, amounting to the in rem effects of a standard sale agreement, along with a corresponding EULA, could be seen as an "indivisible whole," as the sale would be "pointless" if the grapes could not be used by the purchaser.
- According to the EULA, the purchaser of the bag would acquire the right to use the fruit for an unlimited period, against the payment of a fee designed to enable the CPVR holder to obtain a remuneration corresponding to the economic value of the fruit stemming from the protected variety.
- Considered as a whole, the transfer of plant material, performed by the CPVR holder or with his/her consent, accompanied by the conclusion of a EULA, therefore constitutes a "first sale" as required by the exhaustion rule.
- The right of disposal in respect to plant material of the protected variety would be exhausted in case the CPVR holder (i) has authorized, even free of charge, the transfer of that material, and (ii) has conferred the right to use that material, for an unlimited period of time, in exchange for a fee that covers the economic value of both the material of the variety and the IP rights thereto.

4. FINAL REMARKS

The legislative system set forth by the CPVR Regulation seeks to strike a balance between the diverging interests of plant breeders and the general public, through the introduction of a sui generis form of protection for plant varieties subject to a specific set of exceptions and limitations, listed in Articles 15 and 16 BR.

The rationale behind those legislative provisions is evident if we look at, inter alia, the preamble to the BR. There, it is expressly stated that the scope of the breeder's rights should be fairly extended according to the principle of exhaustion, in order to ensure that the protection afforded is not "excessive" and that "free access to protected varieties for the development therefrom, and exploitation, of new varieties" should be safeguarded "in order to stimulate plant breeding." Consequently, "the exercise of Community plant variety rights must be subjected to restrictions laid down in provisions adopted in the public interest" including "safeguarding agricultural production" by means of authorizing farmers "to use the product of the harvest for propagation under certain conditions."

That being said, it may be inferred that the protection afforded by the Community legislator is prominently focused on the economic interests of the breeder, against the underlying need to allow for (i) the free access to breeding innovations, under certain conditions and limitations, (ii) the free movement of goods within the whole territory of the European Union, and (iii) a sustainable technological development within the agricultural field, to the ultimate benefit of the public.

In addition, the statutory exceptions to the breeder's rights, pursuant to Article 15 BR, provide for a specific set of situations where the acts of exploitation relating to plant material of a protected variety cannot be deemed detrimental to the economic interests of the CPVR holder, but rather as capable of delivering positive outcomes, such as in case of experimental use exceptions.

On the other hand, the limitation set forth by Article 16 BR may have considerable impact from a systemic point of view, in all those cases where there is an actual risk that the CPVR in question will be undermined by the performance of any act of exploitation fulfilling the above provision. However, it should be observed that the list of activities preventing exhaustion of the CPVR must be interpreted as comprehensive, which the word "unless" within Article 16 BR seems to suggest.

[94] Ibid., § 49.

[95] As regards the Italian system, for instance, the burden of proof in infringement proceedings is regulated by Article 121(i) of the Industrial Property Code (Legislative Decree no. 30 of 10 February, 2005) expressly providing that "Save for the provision of Art. 67, the burden of proof in infringement proceedings lies on the title holder" (free English translation).

[96] In the United States, see Promega Corp. v. Life techs. Corp., where it was held that "In patent cases, [t]he burden of proving damages falls on the patentee," Lucent Technologies, Inc. v. Gateway, Inc., 580 F.3d 1301, 1324 (Fed. Cir. 2009), "[t]he [patentee] must show his damages by evidence," and Philp v. Nock, 84 U.S. 460, 462 (1873), "[Damages] must not be left to conjecture by the jury. They must be proved, and not guessed at."

[97] See Von Gierke K./Trauernicht in: Metzger/Zech (eds.), Sortenschutzrecht, 2015, p. 37 SortG points 23 et seq.

As a consequence, the general rule is that the breeder's rights will be exhausted after the first sale of the plant material, excepting the rights allowing him/her to control subsequent acts of production and/or reproduction of the protected variety, intended as the core of the CPVR protection, insofar as these rights are meant to preserve the economic interests of the breeder in the residual cases in Article 16 BR.

This notwithstanding, it also appears that two opposing views may be detected at both the Community and the US legislative level: assuming that infringement will occur only when plant variety rights are not exhausted, it could be argued that the whole CPVR system is based on the argument pursuant to which, further to the payment of a royalty as consideration for the exploitation activities relating to the plant material of the variety in question, the exclusive rights of the breeder will be "presumptively" exhausted, except under the circumstances envisaged by the "counter-limitation" of Article 16 BR. The ultimate goal of that article is rewarding (and stimulating) the breeder's efforts in R&D activities aimed at obtaining agricultural improvements with outstanding qualities.

On the other hand, the "presumptive" argument seems not to be applicable, mutatis mutandis, to the US Plant Patent System. There, the title holder seems to benefit from solid legal grounds to adopt misleading and questionable licensing schemes via inclusion of disclaimers such as that addressed in this paper, with the ultimate view of artificially extending control over downstream transactions performed on a "B2C" scale, where the plant material of the protected variety purchased by the consumer is normally intended for final consumption.

The paradigm shift described above may have contradictory outcomes, especially in light of the commonly accepted rules governing the burden of proof in enforcement proceedings relating to IP rights, where both civil law[95] and common law[96] jurisdictions specifically maintain, as a general rule, that the burden of proof for infringement is generally placed on the title holder.

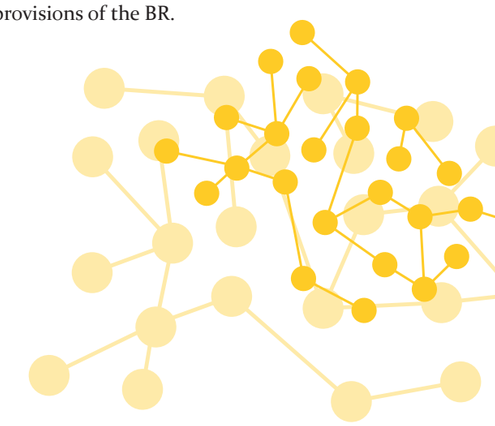
Looking back at the hypothetical posed in the introduction to this paper, it may be concluded that, if the consumer purchases fruit and subsequently sells it to any third party, the breeder's right will be exhausted. Similarly, if the purchaser does reproduce such variety material for private use purposes only, as provided for within Article 15(a) of the BR, the breeder's rights will be exhausted. If the purchaser directly consumes the plant material in question, CPVR exhaustion will inevitably apply.

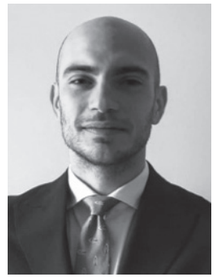
Only in the event of an act involving further propagation of the variety in question, or an export of variety constituents into a third country which does not protect varieties of the plant genus or species to which the variety belongs, will the exclusive rights of the breeder not be exhausted, unless it is shown that (i) further propagation was intended at the time of the disposal, or (ii) the exported material was for final consumption purposes.

Within this tangled regime, few scholars have attempted to define the situations where the breeder's right may be deemed not to be exhausted. In particular, regard should be paid to transactions involving commercial operators and standard "B2C" transactions, where the exhaustion rule may be deemed as more likely to apply, as the plant material is purchased in a grocery store and ultimately intended for final consumption.

A prospective solution to the *impasse* has been suggested, paving the way for higher standards of certainty beneficial to both consumers and stakeholders within the PVR *acquis*. This would involve replacing the cascading solution – which shows effects mainly upstream in the plant breeding value chain – with an effective exhaustion system which would "cover cultivation and further sales leaving necessary freedom for farmers and consumers. On the positive side, the system would be simpler than the current one. The main difference would lie in the burden of proof"[97].

In the meantime, it is likely that a disclaimer on the front of a fruit bag, such as that described in this paper, for sale in EU stores, would be deemed as lacking any value from a legal point of view, insofar as the protection afforded thereby would "exhaustively" be included within the normative provisions of the BR.





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The current status of plant-related IP Rights in Brazil

How to reap the fruits of the protection culture in the agribusiness field

By Isabella Katz Migliori

ABSTRACT

Brazil is recognized as having an important economic market and, also due to its biodiversity, provides countless opportunities for technological developments in several fields. In the Industrial Property arena, it may be reaching its most favorable period, since the Brazilian PTO Patent and Trade Mark Office (INPI) has developed measures to overcome the backlog of examination of patent applications and could be placed soon together with the countries that have already achieved a mature protection culture. In the agribusiness field, Brazil stands out in level of importance worldwide, and the correspondent increasing technological development has started to be accompanied by its due protection. Specifically, regarding plant-related IP rights in Brazil, plant-related technology may be protected by patent and plant varieties (or cultivars) by plant variety protection certificate. However, in order to take advantage of all the opportunities and achieve the best protection – duly reaping the fruits of the protection culture in the country, being of particular relevance to the Agribusiness field –, one must have in mind that the Brazilian IP legal framework has particularities when it comes to this matter, as well as it may be more restrictive than the legal framework observed in other jurisdictions. Thus, without the intention to exhaust each theme, the present article presents an overview on the main topics concerning plant-related IP rights in Brazil.

1. INTRODUCTION

"Brazil is not for beginners", once said Tom Jobim[1], the famous poet, compositor, and singer of "Garota de Ipanema" in about 1960 to a foreign friend, when the country was going through a historical period marked by several contradictions. Until today, this phrase is still used in many different contexts to highlight its complexity.

In the present context, it fits perfectly to illustrate the dichotomy that may be the biggest (and true) cliché assertion about Brazil, a country known for the richest biodiversity, majestic landscapes, hospitable people and soccer, as well as for its social inequality, politics corruption and developing economy. From the general intellectual property (IP) perspective, the same reasoning applies. Brazil can be considered as a pioneer, being one of the 14 signatory countries of the first Paris Convention in 1883 and having already had industrial property rights provisions in its first Constitution in 1824, leading afterwards to the Industrial Property Law in Brazil, which was reformulated a few times into the current one. Despite of that fact, a still delayed IP rights culture, especially within the field of patents, by the society, can be seen in several technological fields.

However, in the Agribusiness sector, this reasoning is rapidly becoming distant from true. Brazil has a vast territory, favorable contour terrains and climate, and a big consumer market, which, in turn, made it possible for the agrobusiness-based economy to grow, putting the country as an important agri-player worldwide. Brazil became in 2018 the 3rd biggest agricultural exporter (under only the United States and the European Union[2]), and until 2019 has been within the 10 biggest economies worldwide according to the Austin Rating[3]. It is undeniable that this cannot be achieved without increased technological development that has started to be accompanied by its due protection.

Regardless of the technology field, although the vast majority of the patent protection in Brazil is still requested by non-residents – only about 17% (annual mean number) of the patents filed between 2008 and 2018 before the Brazilian Patent and Trademark Office (INPI) were filed by residents[4] - over the last few years it has been reported a growing number of applications filed by Brazilian Universities alone or together with companies, and also start-up companies. Also, the increase seen in the productivity of grains has been attributed to the development and the protection of new plant varieties in Brazil[5].

Residents or non-residents, that is, independently of the origin of the technology, all users of the protection systems in Brazil – the Brazilian PTO in particular –, are experiencing one of the most favorable periods of all times. That is because the Brazilian PTO has implemented direct measures to deal with the backlog of examination of patent applications, already reducing and aiming to solve the issue soon. Also, the Institute is constantly publishing new measures – there are several expedited examination procedures in force, including the one directed to "green technologies" – that represent good opportunities for the Applicants to accelerate the examination of patent applications, if it is the case.

Taken together, what is needed for one to able to take advantage of the opportunities given by the Brazilian important economic market and vast biodiversity – that may represent the feedstock to the development of technologies in all fields, and could be of particular importance to the Agribusiness – is to get to know a little bit better the Brazilian IP legal framework regarding plant-related IP rights, for there are particularities that may be more restrictive than those observed in other jurisdictions' legal framework. Thus, without the intention to exhaust each theme, the present article presents an overview on the main topics concerning this matter in Brazil.

2. PLANTS IP RIGHTS IN BRAZIL

2.1. Patents

2.1.1. Matter excluded from patent protection in view of the Brazilian IP Law

The Brazilian Industrial Property Law (Brazilian IP Law, Law No. 9,279/96[6]) expressly excludes from patent protection plants and parts thereof. This is addressed in two particular items of two different articles (10-IX and 18-III). Article 10 sets out what cannot be considered as an invention (or utility model) in Brazil: "IX - the whole or part of natural living beings and biological materials as found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes"; and article 18 sets out what cannot be patented by legal proviso in Brazil: "III – the whole or part of living beings, except transgenic microorganisms[7] that satisfy the three requirements of patentability - novelty, inventive activity and industrial applicability - provided for in article 8[8] and which are not mere discoveries[9].".

Therefore, in practice, the claims directed to the whole or part of plants or seeds, including plant cells, even if transgenic, are not patentable in Brazil for not being considered as an invention or due to simple exclusion from Law by legal proviso.

The same interpretation applies to claims intended to protect extracts as found in nature (enriched extracts, on the other hand, can be protected in some cases[10]), biological sequences (even if obtained in a synthetic form, if they cannot be distinguished from their natural counterpart) and general compositions if characterized solely by comprising a single natural component, such as a plant ex-

1 Antonio Carlos Jobim.

2 MF Magazine, 'Terceiro maior exportador de produtos agrícolas do mundo, Brasil segue como o maior vendedor de soja em 2018', available at: https://blog.mfrural.com.br/terceiro-maior-exportador-agricola-do-mundo-brasil-segue-como-o-maior-vendedor-de-soja-em-2018/

3 Por Darlan Alvarenga, 'Brasil sai de lista das 10 maiores economias do mundo e cai para a 12ª posição, aponta ranking' (G1, 3 March 2021), available at: https://g1.globo.com/economia/noticia/2021/03/03/brasil-sai-de-lista-das-10-maiores-economias-do-mundo-e-cai-para-a-12a-posicao-aponta-ranking.ghtml

4 Information taken from INPI, Indicadores de Propriedade Industrial 2019: O uso do sistema de propriedade industrial no Brasil, April 2020.

5 ABPI, 'A proteção de cultivares e o sucesso do agronegócio', available at: https://abpi.org.br/noticias/a-protecao-de-cultivares-e-o-sucesso-do-agronegocio/

6 Industrial Property Law)

7 The generic term "microorganism" is used for bacteria, archaea, fungi, unicellular algae not classified as plants and protozoa. Thus, among the whole or part of living beings, natural or transgenic, the Brazilian IP Law only allows the patenting of transgenic microorganisms.

8 "Art. 8 - An invention is patentable if it satisfies the requirements of novelty, inventive activity, and industrial applicability."

9 Sole paragraph of article 13: "For the purposes of this Law, transgenic microorganisms are organisms, except the whole or part of plants or animals, which express, through direct human intervention in their genetic composition, a characteristic that is normally not attainable by the species under natural conditions."

10 According to item 4.2.1.1.3 of the Brazilian Guidelines of Examination of Patent Applications in the Field of Biotechnology of April 2020, the extract differentiated from its natural counterpart for being enriched in some of its components, will only be subject to protection when presenting characteristics not normally attainable by the species and resulting from direct human intervention, such as by means of genetic manipulation.

11 INPI, Revista da Propriedade Industrial, (No. 2604 1 December 2020), available at: https://www.gov.br/inpi/pt-br/servicos/patentes/legislacao/legislacao/InstrucaoNormativa118_DIRPABiotecnologia_01122020.pdf

tract. In this later case, the understanding applied, according to the Brazilian Guidelines of Examination of Patent Applications in the Field of Biotechnology of April 2020[11], is that it would confer protection to the non-patentable product itself. In order to circumvent this issue, it is possible to amend the claim so as to add components, parameters or characteristics so as to leave it clear that it actually refers to a composition (a mere diluent may not be accepted).

2.1.2. Biological sequences

On the other hand, there is plenty of plant-related technology that may be protected by patents.

Firstly, it is crucial to highlight the interpretation, as disposed in the Brazilian Biotech Guidelines as mentioned above, when it comes to biological sequences. That is because an important number of patents in the field of plant biotechnology is intended to protect a genetically modified sequence, such as a transgene genetic sequence (nucleotide sequence) that confers to a plant a given characteristic of interest, such as resistance to pathogens, resistance to insects, resistance to herbicides, resistance to drought, improved yield, etc.

As mentioned, in case the sequence, and in particular, the nucleotide sequence, is identical as one as found in nature, even if present in a different organism or has a different role, may fall under the restrictions of the Brazilian IP Law as discussed above.

Thus, in theory, any given modification in the sequence that may confer distinction from natural ones, may be acceptable to circumvent the restrictions regarding protection. This includes unmodified nucleotide substitutions, insertions or deletions in the sequence, provided that the resulting sequence is also not naturally occurring and, in case of deletions, provided that the deletion is not at the ends of the sequence (for then, the resulting sequence would be identical to part of the naturally occurring sequence, thus not being patentable). For this reason, claiming a transgene sequence together with the flanking sequences of the host organism (insertions at the ends of the sequence) may be sufficient to render the resulting sequence as modified, being liable to patent protection.

Another common patentable object of protection in this field of technology refers to cDNA (complementary DNA), which is a DNA sequence produced from RNA as a template. The understanding applied, according to the Biotech Examination Guidelines as mentioned is the following: in case of cDNA produced from messenger RNA (mRNA), if the originating gene has introns (non-coding sequences), the cDNA will be different from the corresponding gene, since cDNA sequence would only comprise the exons (coding sequence), thus being liable to patent protection. On the other hand, in case the cDNA is derived from a mRNA whose originating gene is only composed by exons, the cDNA would be identical to the corresponding DNA, thus not being patentable due to infringing article 10-IX of the Brazilian IP Law.

2.1.3. Processes for generating plants

The same reasoning as explained above directed to products applies to claims related to processes, in that the protection of biological processes considered as natural – that is, processes that may naturally occur in nature – are not liable to patent protection for fitting within the definition of article 10-IX of the Brazilian IP Law (natural biological processes are not considered invention).

Considering that said article could be interpreted as broad for not clearly and precisely defining what could be interpreted as a "natural biological process", once again the Biotech Examination Guidelines tried to better clarify the matter.

According to the Guidelines, "natural biological process" means any process that does not use technical means to obtain biological products or that, even when using technical means, it would be likely to occur in nature without human intervention, consisting entirely of a natural phenomena.

Thus, conventional methods of plant production based on the general steps of selection, breeding and propagation, for instance, are considered natural biological processes. In these cases, the understanding is that although there may be human interference for selecting specific plants of interest for breeding, it is not essential for the process to occur, only accelerating or limiting what could occur in nature. On the other hand, when the plants used for breeding are considered as "unnatural", such as transgenic plants with a heterologous gene, the process could be subject to patent protection. In this case, the human intervention is direct in the genetic composition of plants and has a permanent character.

2.1.4. Matter excluded from patent protection in view of the Biosafety Law

Some technologies are excluded from patent protection, not in view of the Brazilian IP Law, but in view of the Brazilian Biosafety Law (Biosafety Law, Law No. 11,105/05[12]), which expressly rules about this matter. According to article 6-VII of said Law: "6 - it is prohibited: (...) VII - the use, commercialization, registration, patenting and licensing of genetic use restriction technologies.". According to the single paragraph of this item: "For the purposes of this Law, genetic use restriction technologies are understood as any human intervention process for generating or multiplying genetically modified plants to produce sterile reproductive structures, as well as any form of genetic manipulation aimed at the activation or deactivation of plant fertility-related genes by external chemical inducers.".

Thus, any methods leading to plants that are sterile are not patentable. To better clarify that matter, the Biotech Examination Guidelines further elaborated on this understating by stating that the processes and/or genetic manipulation that produce sterile reproductive structures (pollen, ovule, stigma, anther, fruit, and tissues thereof), or that aim at the activation or deactivation of genes related to the fertility of plants by external chemical inducers, fall within the prohibitions of article 6-VII of the Biosafety Law.

Nonetheless, claims directed to products such as vectors, constructs and expression cassettes, as well as processes for restoring the fertility based on the activation/deactivation of genes (provided that they do not involve the use of external chemical inducers) are duly subject to patent protection.

2.1.5. Awareness about Article 32 of the Brazilian IP Law: limitations regarding amendments

When dealing with patent protection, there is a particular understanding applied for Article 32 of the Brazilian IP Law – regarding amendments in the set of claims after the examination is requested – that must be mentioned. This is because, as can be seen from the overview above, there are some restrictions in the Brazilian IP Law that may require adequate analysis of the scope of protection claimed and the performance of eventual amendments in the set of claims in order to obtain the maximum protection possible for each technological development.

Article 32 of the Brazilian IP Law itself states: "In order to better clarify or define the patent application, the applicant may perform amendments until the examination is requested, provided that these are limited to the matter initially disclosed in the application.". However, the understanding applied for such article, as disposed on Resolution No. 093/201313, is that after the Examination is requested, amendments in the set of claims can only be performed in order to better define or to limit the scope of protection of the set of claims for which examination was requested. Thus, amendments that broaden or change its scope of protection (for instance, adding a new category of claim, or a new independent claim, even if based on the specification) cannot be performed after the examination request. Such limitation also applies for divisional applications. The scope of protection of the set of claims of the divisional application shall be limited to the scope of protection of the set of claims for which examination was requested.

In view of that, differently from other jurisdictions, it is usually advisable to wait until closer to the deadline date of the examination request, when the applicant usually had the chance to have the application already examined elsewhere, and to properly evaluate the scope of protection of interest, to perform amendments in the set of claims just before requesting the examination without incurring the limitations imposed by the understanding of article 32 as mentioned.

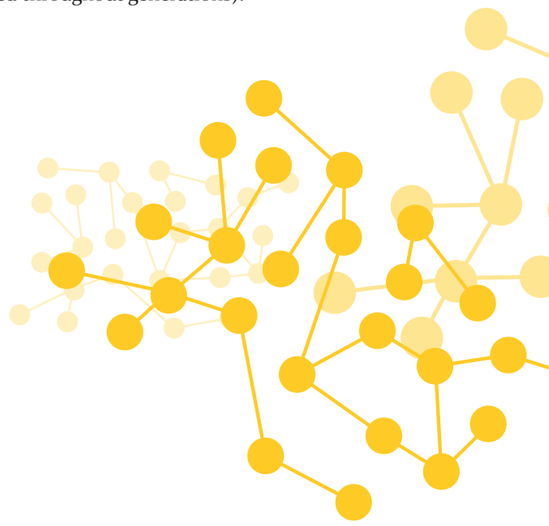
2.2 Plant Variety Protection

As mentioned, the Brazilian IP Law (Law No. 9,279/96) expressly excludes from patent protection plants and parts thereof. However, the protection of plant varieties (or cultivars), as disposed in the Brazilian Plant Variety Protection Law, Law No. 9,456/97[14], regulated Decree No. 2,366/97[15], may be obtained by the Plant Variety Protection Certificate issued by the National Cultivar Protection Service (SNPC) of the Ministry of Agriculture, Livestock and Food Supply in Brazil (MAPA). This is a sui generis type of protection originated from the intergovernmental organization UPOV – the International Union for the Protection of New Varieties of Plants – of which Brazil is a member.

The plant variety protection can be interpreted as complementary to the patent protection, in that the objects of protection conferred by both types of rights (patent protection and plant variety protection) do not overlap. Actually, if possible, in case the technological development allows it, both types of protection are advisable.

As imagined, whereas the patent can indirectly protect the plant produced by or comprising technology protectable by patent, the protection conferred by a cultivar will directly fall on the reproductive material or vegetative multiplication of the entire plant. Also, the certificate guarantees its owner, with a few exceptions, the right to commercial reproduction in the Brazilian territory, being forbidden to third parties, during the term of protection, production for commercial purposes, offering for sale or commercialization, of the propagating material of the cultivar, without the owner's permission.

By general definition based on the understating of the Law in question, a cultivar, which may be produced by any technique (traditional or genetic engineered), is the variety of a plant species that is clearly distinguishable from other cultivars by minimum margin of descriptors, that is, features (morphological, physiological, biochemical or molecular inheritable characteristics) of interest. In order to be protectable, the cultivar as to the descriptors must be distinct (from others of the same species), homogeneous (uniform if planted in commercial scale) and stable (preserved throughout generations).



[12] Law No. 11,105 of March 24, 2005 (Law on Biosafety).

[13] Resolution No. 093/2013 of June 10, 2013 ("Guidelines on the applicability of article 32 of Law 9279/96 in patent applications, within the scope of the INPI").

[14] Plant Variety Protection Law, Law No. 9,456/97, of April 25, 1997.

[15] Decree No. 2,366, of November 5, 1997.

3. IP RIGHTS INVOLVING COMPONENTS OF THE BRAZILIAN GENETIC ASSET AND ITS ASSOCIATED TRADITIONAL KNOWLEDGE

3.1. Brief historical context

As one may know, biodiversity is one of the main resources of the world, and it is fading away quickly. Many countries have started in the near past conservation measures in large scale in order to try to reverse the damages caused by human lifestyle. Brazil is, of course, an important player in this scenario, for it is considered to be the most biodiverse country in the world, having many different biomes and with a climate that favors the development of many different species.

Therefore, in this context of protection and conservation of the biodiversity worldwide, it is pertinent to mention the Convention of the Biological Diversity (CBD), established in 1992 during ECO-92 in Rio de Janeiro, which was the legal milestone that ultimately led to the current Biodiversity Law in Brazil (Law No. 13,123/15[16]), regulated by Decree 8,772/16[17].

The CBD is an international multilateral treaty of the United Nations which establishes norms and general principles for the protection and use of biological diversity by the signatory countries, respecting the sovereignty of each nation over the patrimony existing in its territory. The general and basic principles of the CBD[18] are: (i) the conservation of biological diversity; (ii) sustainable use of its components; and (iii) fair and equitable sharing of the benefits derived from the economic exploitation of genetic resources.

Historically, the legal dispositions of the CBD were internally incorporated in the Brazilian legal system by means of a Provisional Measure No. 2,186-16/2001[19], which was the legal framework in force in Brazil until the current Law came into force, in 2015.

The Provisional Measure was innocuous because it was almost impossible to be complied with. Among its dispositions, it established that in order for one to perform any research or technological development over a sample of the Brazilian genetic asset, it was necessary to request previous authorization to the Genetic Heritage Management Council (CGEN). it used to take years years for the authorization to be granted. Thus, the users used to either give up using samples of the Brazilian genetic asset or used to access them in disagreement with the Provisional Measure. Also, apart from the Brazilian biodiversity species that were considered endemic, no one could really know at that time what would constitute a sample of the Brazilian biodiversity, and the simplified understanding applied to using the Brazilian traditional knowledge was mainly literally obtaining the knowledge in loco from the indigenous populations, traditional communities or farmers.

So when the new Law came into force, correcting many of the former legal deficiencies, it was a milestone. It simplified a lot the proceedings predicted by the old Provisional Measure and established many definitions that were lacking. One of the main innovations brought by the new Law is that, for the majority of activities of access, no previous authorization by CGEN is needed. The new Law established an electronic registration system (SisGen), and a self-declaratory registration of the activities is sufficient for most of the cases of access.

In summary, the new Law and Decree address:

- the access to the genetic assets, access to the associated traditional knowledge;
- access to technology and technology transfer;
- economic exploitation of finished product or reproductive material;
- sharing of the benefits derived from access and remittance abroad of components of genetic assets.

In case one is to perform any of these activities, one must be aware that there are dispositions to be complied with.

The legal framework may lead to additional administrative and regulatory bureaucracy, especially for researchers (companies and individuals), but in the end, it is only intended to achieve, in practice, the three basic principles of the CBD as mentioned.

3.2. The link between Brazilian biodiversity and the patent system

But what does all of this have to do with patents? In general terms, both the former Provisional Measure and the new Biodiversity Law somehow conditioned the granting of IP rights to comply with the terms of the biodiversity legal framework in force. This ended up with the Brazilian PTO becoming a "checkpoint" for verifying this matter in Brazil. Currently, to comply with the provisions of the Biodiversity Law, the user, at the moment of requesting the intellectual property right, must inform whether there was access to Brazilian genetic assets or its associated traditional knowledge, as well as if there is an access registration. Thus, in summary, it is not possible to file a patent without this information in hands.

It is important to state that the Brazilian Biodiversity Law, which in turn influences the research and technological developments with Brazilian biodiversity and the possible IP rights derived from it, rules the country as a provider of the biodiversity resources. In this sense, exotic species (and its use as biological resources) are not subject to this Law. But this does not mean that that the use of exotic species is not subject to equivalent laws in their countries of origin.

This is where the Nagoya Protocol[20] comes in, aiming precisely to regulate the relationship between resource provider countries and user countries, by ensuring the reciprocity of obligations and rights between them. Brazil recently ratified this agreement on March 4th 2021 as a supplementary agreement to the CBD, ruling about one of its pillars, namely the fair and equitable sharing of benefits derived from access to the genetic assets.

In view of that, Brazil should soon establish legal rules to ensure that the laws of the countries providing international resources are also complied with in the national territory. Naturally, this reciprocity will also be demanded by Brazil, when other countries use Brazilian resources.

3.2.1 As to the definitions

To know if one is performing any of the activities predicted for in the Brazilian Biodiversity Law and Decree, it is important to understand how these dispositions define the activities.

Access to the Brazilian genetic asset, to begin with, is the research or the technological development carried out on a sample of Brazilian genetic assets. Thus, for instance, sequencing the genome of a species considered as derived from the Brazilian genetic asset would fall under the definition of access. However, contrary to the wording, access does not necessarily mean that the genome must be part of the research.

As to the species which are considered as derived from the Brazilian genetic asset, it is important to point out that this is still a complex topic. In a simplified manner, the Brazilian genetic assets are understood as the ones as follows:

- The Brazilian endemic species, as found on national territory, on the continental shelf, in the territorial sea and in the exclusive economic zone;
- Native species, as found in in situ conditions in the Brazilian territory, regardless of their collection site (e.g. transboundary species);
- Domesticated or cultivated species, given that they have acquired distinctive characteristics of their own in the Brazilian territory;
- The same species as above, even if in ex situ conditions (for instance from collections);
- As to microorganisms, the new Law brought a new understanding: any micro-organism isolated in the national territory, on the continental shelf, in the territorial sea and in the exclusive economic zone will be considered as Brazilian genetic asset.

The complexity mainly lays on the fact that it is not clear which species have acquired distinctive characteristics of their own in the Brazilian territory. Nonetheless, this an ongoing discussion with new understandings being constantly published on this matter and particular experts' consultation may be needed.

As to the access to the associated traditional knowledge, the new dispositions define it as the research or technological development carried out on traditional knowledge associated with genetic asset that enables or facilitates access to genetic asset, even if obtained from secondary sources such as fairs, publications, inventories, films, scientific articles, registers and other forms of systematization and registration of associated traditional knowledge.

It is important to keep in mind that the new dispositions brought another new understanding due to the aforementioned definition, it being possible to access the associated traditional knowledge without even leaving the lab.

Traditional knowledge associated with genetic assets is the information or practice of indigenous population, traditional community or traditional farmer on the properties or direct or indirect uses associated with genetic assets. The associated traditional knowledge can be of identifiable origin, when it is possible to find or link the origin of an associated traditional knowledge to at least one indigenous population, traditional community or traditional farmer. It can also be of non-identifiable origin, when it is not possible to find or link the origin of an associated traditional knowledge to at least one indigenous population, traditional community or traditional farmer.

The access to the associated traditional knowledge of identifiable origin is conditioned to the obtainment of prior informed consent from such communities or populations or farmers. Many communities, populations or farmers could be considered as the holders of the knowledge, but the prior informed consent must be celebrated with at least one of them, which is then considered as the provider of the knowledge.

3.2.2. As to the registration

According to the new dispositions, the following activities should be registered:

- Access to genetic assets or associated traditional knowledge within the country performed by a natural person or national legal entity, public or private. The access by a foreign natural person is forbidden by Law.
- Access to genetic assets or associated traditional knowledge by legal entities based abroad, associated with national institutions for scientific and technological research, public or private. This is important, for a foreign institution to perform access, it must be associated with a national institution for scientific and technological research.
- Access to genetic assets or associated traditional knowledge performed abroad by a natural person or national legal entity, public or private.
- Remittance of samples of genetic assets abroad with the purpose of access, in the two cases just above.
- Sending of samples containing the genetic asset by a national legal entity, public or private, for performing services abroad as a part of research or technological development.

It is important to point out that the registration must be carried out prior to the shipment, or to the requirement of any intellectual property right, or to the marketing of the intermediate product, or to the disclosure of the final or partial results, in scientific or communication means, or to the notification of finished product or reproductive material developed as a result of access.

[16] Biodiversity Law, Law No. 13,123/15 of May 20, 2015.
[17] Decree No. 8,772/16 of May 11, 2016.
[18] The complete CBD text can be found at: https://www.cbd.int/convention/text/
[19] Provisional Measure No. 2,186-16/2001 of August 23, 2001.
[20] The complete Nagoya Protocol text can be found at: https://www.cbd.int/abs/text/

After the registrations just mentioned, it will go under an administrative verification process in order to guarantee that the registration was duly performed according to the Law. Also, the user may request the certificate of regularity of access. It is recommended that such certificates be requested before performing any of the activities mentioned above, for incorrect registration may lead to cancelation of registry and/or penalties.

3.2.3. As to the benefits sharing

Although the activities as previously observed require the registration in SisGen, not every research or technological development derived from access to Brazilian genetic assets or its associated tradition knowledge will be subjected to benefits sharing.

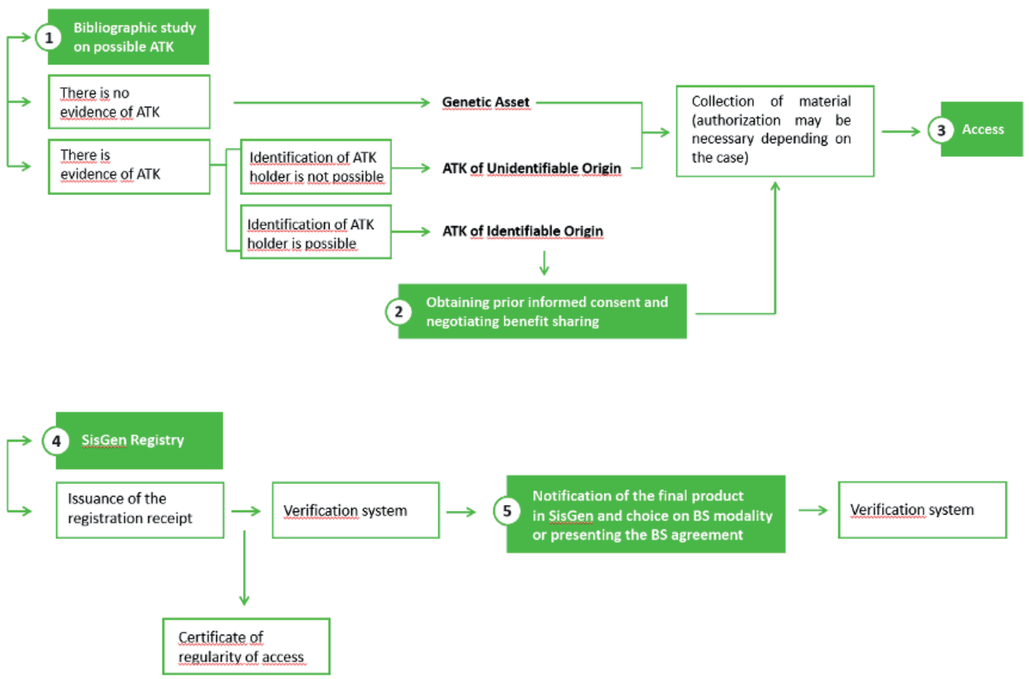
According to the new dispositions, only the following will share benefits derived from access:

- The producer of the finished product or the producer of the reproductive material derived from access to genetic asset or associated traditional knowledge, even if produced outside the country, regardless of who has previously made the access.
- In the case of a finished product the genetic asset or associated traditional knowledge component must be one of the main elements of added value (elements whose presence in the finished product is decisive for the existence of the functional characteristics or for the formation of the marketing appeal).

It is important to point out that when a finished product or reproductive material is the result of different accesses, they will not be considered cumulatively for the calculation of benefits sharing. Also, in case the finished product or the reproductive material has not been produced in Brazil, the importer, subsidiary, controlled, colligated, linked company or commercial representative of the foreign producer in the national territory, or in the territory of countries with which Brazil has an agreement to this end, responds jointly with the manufacturer of the finished product or the reproductive material for the benefit sharing.

Finally, there are two modalities predicted in the new dispositions for benefits sharing: monetary or non-monetary, depending on the case. When monetary, the payment will be to the Federal Government, by means of the National Benefit Sharing Fund (FNRP).

For instance, in the case of genetic assets, one can choose between the modalities – monetary or non-monetary. In case of monetary, the Brazilian Biodiversity Law determines that the amount in question is 1% of the yearly net income to the FNRP of the Federal Government, whereas in case it is non-monetary, it will be equivalent to 0,75% of the yearly net income, according to a benefits sharing project defined with the Federal Government (it must be among related ones) or 1% in the remaining cases (if the project is different from the related ones). In case of associated traditional knowledge, if identifiable, a part of the total amount is freely negotiated with the provider + another part is monetary: 0,5% of the yearly net income to the Fund of the Government. In case of associated traditional knowledge of non-identifiable origin, it is always monetary, and the amount in question is 1% of the yearly net income to the FNRP of the Federal Government.



3.2.4. Take home message

When performing research with Brazilian genetic asset, that may or may not lead to an intellectual property right, the simplified recommended steps (as illustrated and summarized in the chart below) should be followed.

Step 1 is performing a bibliographic study on possible traditional knowledge associated with the Brazilian genetic asset to be studied. In case there is no evidence of associated traditional knowledge (ATK), then, one is performing access to the genetic asset. In case there is evidence of associated traditional knowledge, one must determine if it is of identifiable or non-identifiable origin. In case of identification of origin, step 2 is obtaining prior informed consent and negotiating the benefits sharing.

Afterwards, for all the three modalities (access to genetic asset, access to the associated traditional knowledge of identifiable or non-identifiable origin) it is possible to collect the sample (authorization may be needed from particular Brazilian authorities, depending on the case) and to perform the access, which is step 3.

In case the research is fruitful, step 4 is performing the registration in SisGen system, as mentioned. It will automatically issue the registration receipt, which is sufficient to start performing the activities mentioned that must be preceded by registration. But since the registration will undergo verification procedure, it is recommended that the user actively requests the issuance of the certificate of regularity of access before performing the activities mentioned that must be preceded by registration, such as, for instance, requesting any intellectual property right.

Finally, step 5 concerns the production of a product. If a product is produced, one must notify the final product at the SisGen system and choose the benefits sharing (BS) modality or present the benefits sharing agreement, if it is the case. This notification will undergo the verification system as well.

4. CONCLUSION

In Brazil, the plant-related IP rights are conferred by patents or by plant variety protection, which protect distinct and complementary aspects of the technology.

Despite having particularities and some restrictions as to the protection of a few aspects related to plant technology by patents, there are transparent guidelines and possibilities to circumvent some of the restrictions.

However, knowing how to claim the protection is as important as when to do it. Considering the restriction of the Brazilian IP Law regarding amendments after the examination is requested (after the examination request, amendments in the set of claims are only allowed to better define or to limit the subject matter of the set of claims for which examination was requested), it is advisable that, in case of complex technology, which is almost always the case with biotechnology and particularly biotechnology within the agribusiness, a technical revision of the case is performed by a patent specialist so as to evaluate the scope of interest in view of the invention and if amendments that may not be allowed after, be performed before the examination request.

Finally, when it comes to performing research or technological development with components of the Brazilian biodiversity, it is important to have in mind that there is a Law in force and particular measures should be taken (including before the request of any intellectual property right) and could even lead to the necessity of benefits sharing in Brazil.

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Conflicts between pharmaceutical patents and access to medicine during the pandemic

By Iyad Al Khatib

ABSTRACT

The coronavirus pandemic has changed many aspects of life. Revising contemporary laws and legal systems is inevitable to survive the current and future pandemics. The first paramount concerns are human life and health. An associated consideration is the financing of related medical solutions inter alia vaccines, antivirals, and antiretrovirals. These issues conflict with each other in the legal space intersecting between intellectual property (IP) and human rights. Humans have the legal right to 'access to medicine'. On the other hand, pharmaceutical industries have the right to patent their products, which unfortunately could make medicine prohibitively expensive. During pandemics, choosing to give the medicine/licenses for free sounds like the best ethical solution, but it comes with serious risks like compromising the existence of the sources of research and development (R&D) needed to prepare for future outbreaks. Therefore, a balance is needed. Consequently, more legal research is a requisite. Efforts by policymakers, practitioners, researchers, and related institutions are essential. The investigation tackles these issues on an international level, and it renders special focus on the EU in some sections. This paper locates the relevant problems that need attention, collects related provisions, and propounds recommendations.[1]

1. INTRODUCTION

A principal human right is that "to life," which is mentioned in international human rights legal instruments such as Article 6(1) of the International Covenant on Civil and Political Rights (ICCPR)[2] and Article 2 of the European Convention on Human Rights (ECHR).[3] This right encompasses many related rights, *inter alia* access to essential healthcare services and products. However, significant growth in pharmaceutical patents has led to increased drug prices and may decrease people's ability to purchase medicine,[4] threatening "access to medicine." Disputes in this area, between states, pharmaceutical companies, patients, and investors, have occurred not only because of trade issues but also in relation to human rights, *inter alia the case of Novartis AG (Switzerland) v. Union of India & Others*[5] (discussed in subsection 5.2.2). During pandemics, the clash between patents and human rights can lead to unforgivable delays in delivering medicine, more suffering, and loss of lives. This is evident in the current worldwide trials regarding the IP rights of manufacturers of COVID-19 vaccines.[6] The legal regimes applicable in such conflicts are patent laws, such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS)[7] Agreement, domestic laws, international human rights laws (IHRL),[8] including the ECHR, and other human rights instruments. However, it is up to courts to decide whether to consider IHRL in a decision-making process. The reason for the growth in patent applications is the exclusivity right, which means that protection of inventions can generate large revenue. An important legal instrument that adds to the incentive for innovators is TRIPS, which sets minimum standards of legal protection for IP, to be provided by each signatory state.[9] Hence, TRIPS has an impact on the legal practices of states and unions (e.g., EU) in the field of patents.

The latest statistics show that pharmaceutical patent applications at the European Patent Office (EPO) grew by 4.4% between 2018 and 2019.[10] According to the Global Use of Medicines report from the IQVIA Institute for Human Data Science, the global pharmaceutical market grew to USD 1.2 trillion in 2018.[11] The report predicted the global market growth in the coming few years to be 4–5%, reaching USD 1.5 trillion (based on invoice pricing).[12] The pharmaceutical industry has huge costs for R&D processes, for which patents are meant to provide some compensation.[13] However, manipulations of the market exclusivity that comes with a patent raise ethical concerns, since patent-protected medicines have no price thresholds or competitors for about twenty years[14] (also protected by TRIPS). The Tufts Center for the Study of Drug Development estimates that around USD 2.6 billion and a ten-year commitment are needed for a new medicinal drug, from the research phase until its release to the market.[15] Hence, pharmaceutical companies need to set a suitable price to get a return on investment (ROI). This makes some medicines inaccessible to some populations, creating a dilemma.

The last seventy years have witnessed the development of human rights law, which has begun to touch new fields, including patents. The general perception is that the problem of medicine costs exists only in developing countries. However, a study in the USA reveals that "Americans continue to suffer the highest prescription drug costs of anyone in the world (...) And even though drug prices tripled over the last decade, analysts predict they will double again in the next ten years."[16] One in four Americans is unable to fill prescriptions because of high medicine prices.[17] According to the study, this problem is due to "the patent system."[18]

When conflicts threaten the availability of a vital drug to a group of patients (e.g., HIV[19]/AIDS[20] victims) in a region, this calls for leveraging every possible way of managing this problem: healthcare (time to reach a decision and accessibility), legal issues (conflicts of law), policies (public interest and morality), economic considerations, and (pharmaceutical companies') business benefits and sustainability. When healthcare faces a pandemic (e.g., HIV/AIDS[21] , SARS[22], COVID-19[23]), conflicts related to patent rights for antiretrovirals,[24] antivirals[25] and vaccines[26] can have grave consequences. Human life must have the highest priority in such disputes. If prices soar, we would go against the policy of protecting medicine accessibility. Balancing patents against human rights in pandemic times is essential.

1 Acknowledgement is made to Professor Marianne Levin at Stockholm University, Sweden, for fruitful advice and contributions through many discussions, the idea of including TRIPS Articles 8 and 31bis, and the analogy with the three cases at the Court of Justice of the European Union (CJEU): Funke, Pelham, and Spiegel.

2 International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976), 999 UNTS (ICCPR) art 6(1).

3 Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (ECHR), (4 November 1950) Art. 2.

4 KT Richards, KJ Hickey, and EH Ward "Drug Pricing and Pharmaceutical Patenting Practices" CRS Report Prepared for Members and Committees of Congress, R46221 (Congressional Research Service 11 February 2020) 1.

5 Novartis AG v. Union Of India & Others (Civil Appeal Nos. 2706–2716) arising out of SLP(C) Nos. 20539–20549 of 2009) Indian Supreme Court (1 April 2013).

6 See Nasos Koukakis, "Countries worldwide look to acquire the intellectual property rights of Covid-19 vaccine makers" Our New Future - Special to CNBC (CNBC 22 January 2021).

7 WTO, the TRIPS Agreement and the Conventions referred to in it (entered into force on 1 January 1995).

8 OHCHR, "International Human Rights Law" (UN) 1996–2020.

9 WTO, Overview: the TRIPS Agreement (1 January 1995).

10 MarketWatch, "Pharma and OTC Market 2020 Growing Rapidly with Modern Trends, Development, Investment Opportunities, Size, Share, Revenue, Demand and Forecast to 2026 Says Industry Research Biz" (27 February 2020) Market Watch.

11 IQVIA, "Global pharma spending will hit $1.5 trillion in 2023" (29 January 2019) Pharmaceutical Commerce, para 1.

12 Ibid.

13 Bruce Lehman, "The Pharmaceutical Industry and the Patent System" (2003) International Intellectual Property Institute.

14 Elle Mahdavi, "Patents and the Pharmaceutical Industry" (26 May 2017) California Review Management.

15 Ibid.

16 Tahir Amin, "The problem with high drug prices isn't 'foreign freeloading,' it's the patent system" (2018) CNBC.

17 Bianca DiJulio, Jamie Firth, and Mollyann Brodie, "Kaiser Health Tracking Poll" (20 August 2015) KFF.

18 Amin (n 16).

19 See the HIV definition in WHO, What is HIV? (HIV/AIDS, 27 November 2017), stating that the "human immunodeficiency virus (HIV) targets cells of the immune system (...)."

20 See the AIDS definition in WHO, Is AIDS different from HIV? (HIV/AIDS, 27 November 2017), stating that "Acquired immunodeficiency syndrome (AIDS) is a term that applies to the most advanced stages of the HIV infection."

21 WHO, Data and Statistics (HIV/AIDS, 12 April 2020), considers HIV/AIDS a pandemic – a global epidemic; Myron S. Cohen, Nick Hellmann, Jay A. Levy, Kevin DeCock, and Joep Lange, "The spread, treatment, and prevention of HIV-1: evolution of a global pandemic" (April 2008) The Journal of Clinical Investigation 118 (4) 1244–54.

22 See WHO, "SARS (Severe Acute Respiratory Syndrome)" (WHO International travel and health, UN), stating that SARS is a type of coronavirus (SARS-CoV) identified in 2003 and that "An epidemic of SARS affected 26 countries and resulted in more than 8,000 cases in 2003" https://www.who.int/ith/diseases/sars/en/ accessed 29 April 2020.

23 See ECDC (European Center for Disease Prevention and Control), Stockholm, Coronavirus disease 2019 (COVID-19) pandemic: increased transmission in the EU/EEA and the UK - seventh update (Rapid Risk Assessment, 25 March 2020), stating that COVID-19 stands for COrona VIrus Disease 2019 and that it had caused a pandemic.

24 See NIH, "Antiretroviral," (HIV/AIDS Glossary, 28 July 2020), definition as "A drug used to prevent a retrovirus, such as HIV, from replicating."

25 See WHO, Antiviral drugs for pandemic (H1N1) 2009: definitions and use (Emergencies preparedness, response, Diseases, 22 December 2009), defining antiviral drugs as "medicines that act directly on viruses to stop them from multiplying."

26 See para 2 in CDC, "Immunization: The Basics" (CDC Vaccines & Immunizations), stating that a vaccine is "A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease" https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm accessed 29 April 2020.

Pandemics strike by surprise, and if policies and laws are not prepared, trying to fix problems in "real time" may lead to more suffering and death. Some fields of concern include the resolution of conflicts between laws, whether exceptions to patents are needed, and the pros and cons of compulsory licenses (CL). In influenza and similar virus pandemics, vaccines are the principal measure for safe and effective mitigation.[27] Meanwhile, pharmaceutical companies have an interest in generating profit. The vaccine market share is very attractive to pharmaceutical industries, since it has increased six-fold over the past two decades (according to AB Bernstein) reaching a value of more than USD 35 billion today.[28] Moreover, the COVID-19 pandemic is increasing interest in the fast-growing vaccine industry.[29] Since 2020, some governments, *inter alia* those of Canada, Germany, France, and Chile, have started to adopt extraordinary measures such as amending laws and passing new legislation to allow for CL, to tackle the health crises created by COVID-19.[30] Moreover, South Africa and India have asked the World Trade Organization (WTO) to suspend IP protections for COVID-19 drugs, vaccines, and diagnostics for the duration of the pandemic.[31] The US President Biden was urged not to accept this request.[32] Political, economic and legal aspects all come into the picture, and CL cannot provide a global solution.

From the legal viewpoint, the aforementioned conflicts can be traced back to the rare intersections between patent laws and IHRL. We face the dilemma of choosing between two desirable laws, without any satisfactory solutions. Identification of provisions common to both patent law and human rights legal instruments is needed. The legal instruments in which such overlap should be investigated are TRIPS and IHRL (including relevant EU laws). The dilemma creates legal questions in pandemics, such as: (i) Is there a human right of "access to medicine," even though this phrase is not found in any provision of applicable laws? (ii) How can we choose between CL, patent exceptions or other methods? (iii) How do we ensure consistent court interpretations of the conflicting laws?

This paper does not consider instruments of international humanitarian law, which might sometimes be confused with IHRL, and does not include issues of compensation to patients or for pharmaceuticals. The legal instruments considered are: the ECHR;[33] the Universal Declaration of Human Rights (UDHR);[34] the ICCPR;[35] the International Covenant on Economic, Social and Cultural Rights (ICESCR);[36] the Convention on the Elimination of all forms of Racial Discrimination (CERD);[37] the WTO TRIPS Agreement;[38] and various EU norms.

2. THE HUMAN RIGHT "TO HEALTH"

The meaning of the phrase *right to health* is not difficult for most of us to grasp, but it can sometimes be confusing to interpret legally. There is no statement or rule in the human rights legal instruments on this, as such, or that includes wording that clearly articulates the right of a human to be healthy.[39] For many biological and behavioral reasons, such as genetics and accidents, it is not within the capacity of authorities to ensure that everyone lives in full health.[40] The word "medicine" is not found in any of the human rights provisions. However, IHRL protects *inter alia* the rights to security and safety of a human being, to own property, to private and family life, and to enjoying the "highest attainable standards of health."[41] Hence, we refer to the right "to health" as the right "to the highest attainable standards of health." Within IHRL, this research work investigates a smaller subset of instruments: the UDHR, the ICCPR, the ICESCR, the CERD, and EU conventions. The right to health is provided for in Article 25 UDHR and Article 12 ICESCR; the key phrases are underlined below. Unfortunately, the UN Members did not vote for a legally binding convention at the adoption of the UDHR, but rather a statement of "common standard of achievement for all peoples of all nations."[42] Some instruments, such as the ICESCR and the ICCPR, translate the UDHR principles into a legally binding form.[43]

[27] WHO, Vaccination (Health topics, Communicable diseases, Influenza 2020).
[28] Yun Li, "Coronavirus highlights the $35 billion vaccine market. Here are the key players" (23 February 2020) CNBC Markets.
[29] Ibid.
[30] Adam Houldsworth, "The key covid-19 compulsory licensing developments so far" Law Business Research (IAM 7 April 2020) para 1.
[31] Doctors Without Borders, "Governments make request to WTO for intellectual property waiver for all countries until herd immunity is reached" News and Stories (DWB 7 October 2020) https://www.doctorswithoutborders.org/what-we-do/news-stories/news/india-and-south-africa-propose-no-patents-covid-19-medicines-and-tools accessed 3 March 2021.
[32] The Economic Times, "President Biden urged not to accept India and South Africa proposal at WTO on COVID-19" Business News, International (6 March 2021) para 1.
[33] ECHR (n 3).
[34] UNGA Res 217 A (adopted 4 November 1950, entered into force 3 September 1953) UDHR.
[35] ICCPR (n 2).
[36] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR).
[37] Convention on the Elimination of All Forms of Racial Discrimination (adopted 21 December 1965, entered into force 4 January 1961) 660 UNTS 195 (CERD).
[38] WTO (n 7); WTO, A Handbook on the WTO TRIPS Agreement (WTO and CUP 2012).
[39] Daniel Moeckli, Sangeeta Shah, and Sandesh Sivakumaran, International Human Rights Law, 3rd ed (OUP 2018) 195.
[40] Ibid.
[41] Bruce Oswald, Helen Durham, and Adrian Bates, Document on the Law of UN Peace Operations (OUP 2011) 68–70; ECHR (n 3) Art 8.
[42] UNGA (n 34) Preamble.
[43] Ibid.
[44] ESC - European Social Charter (Revised), "The right to protection of health" (European Treaty Series no 163 Council of Europe) art 11; ECHR (n 3) Art 2; EC, Charter of Fundamental Rights of the European Union (2000/C 364/01) Art 35.
[45] Moeckli (n 39) 196; CESCR General Comment 14, para 12.

UDHR Article 25(1)
(1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services (...).

ICESCR Article 12
1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties (...) include those necessary for:
(...)
(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

ICERD Article 5(e)(iv)
In compliance with (...) article 2 of this Convention (...) the enjoyment of the following rights:
(...)
(e) Economic, social and cultural rights, in particular:
(...)
(iv) The right to public health, medical care, social security and social services; (...).

The major relevant EU provisions are Articles 11 and 13 of the European Social Charter, which form the basis for Article 2 ECHR on the right "to life" and Article 35 EU Charter of Fundamental Rights on "Health care" (below). Moreover, Article 2 ECHR discusses a similar right as that in Article 2 of the EU Charter of Fundamental Rights. Below are some excerpts of the relevant texts.

EU Articles[44]
- European Social Charter- ESC (Revised)
Article 11 – "The right to protection of health
With a view to ensuring the effective exercise of the right to protection of health, the Parties undertake, (...) inter alia:
1. to remove as far as possible the causes of ill-health;
(...)
3. to prevent as far as possible epidemic, endemic and other diseases, as well as accidents.

- ECHR Article 2
Right to life
1. Everyone's right to life shall be protected by law. (...)

- EU Charter of Fundamental Rights Article 35
Health care
Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. (...)

Article 25 UDHR and Article 12 ICESCR rank highest, as they are conventions, at the top of the hierarchy of legal instruments. In Article 25 of the UDHR, we can make note of the important phrase "medical care." Although the UDHR is not legally binding, the phrase "medical care" gives a clear indication that medicine is part of such care. Moreover, ICESCR Article 12 gives no doubt about the human being – in a Member State – having the right to enjoy public healthcare, including medicine accessibility. In the EU, it is legally binding for a Member State to provide such access. Can legal reasoning lead to different interpretations of the right of "access to medicine"? Clearly, public health services and medical care cannot be delivered if there is a lack of medicine accessibility. Although there is no specific provision on *the right of "access to medicine,"* the above is enough to indicate that such access is part and parcel of human rights.

3. IHRL LEGAL OBLIGATIONS FOR THE RIGHT "TO HEALTH"

The right to health creates obligations on State Parties. The parties' fulfillment of such IHRL obligations is clearly stated in four steps in Article 12(2) ICESCR (above). The Committee on Economic, Social and Cultural Rights (CESCR) specifies, in General Comment 14, that the right to health involves four points that become obligations for State Parties.[45] The following four points define those legal obligations and examine their applicability in pandemics:

1. The first is the *availability* of healthcare and medicine. State Parties have an obligation to ensure availability of a functioning public health system and healthcare facilities, goods, and services in sufficient quantities. Is this possible in pandemics? We have witnessed many states failing to provide for even simple needs, e.g., facemasks and ventilators. Do State Parties' politicians have enough time and resources to lead investments/projects on vaccines or antivirals? In the last hundred years, humans have suffered tribulations and delays due to the lack of pandemic emergency laws and systems that aid governments in tackling outbreaks quickly. For instance, during the HIV/AIDS pandemic, it took many years before new laws and regulations saw the light. This paper identifies a problem in the issue of reducing the time-to-market (including R&D) for a vaccine (i.e., the length of time for it to become available). However, an available drug does not guarantee access for patients.

2. The second obligation is *accessibility* to health facilities, goods, and services for all humans. "Accessibility has four overlapping dimensions: (1) non-discrimination; (2) physical accessibility; (3) economic accessibility (affordability) and (4) information accessibility (the right to seek, receive, and impart information and ideas concerning health issues)."[46] An example of a problem is the high price for AIDS antiretroviral drugs protected by the patent system in the USA, EU, and most State signatories of TRIPS. The challenging problem is market-price regulation. It requires exceptions in thinking about pricing. In pandemic times, patent law exceptions must be reconsidered.

3. The third is *acceptability*, i.e., "all health facilities, goods, and services must be respectful of medical ethics and culturally appropriate, sensitive to gender and lifecycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned."[47]

4. The fourth obligation is the *good quality* of health facilities, goods, and services.

The CESCR urges all State Parties to adopt, design, and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the entire population. Strategies and plans of action should be devised and continually reviewed on the basis of a participatory and transparent process.[48] They should encompass methods for follow-up, such as right-to-health indicators and benchmarks. Moreover, everyone should be ensured access to essential drugs, as defined under the World Health Organization (WHO) Action Programme on Essential Drugs.[49]

In the current COVID-19 pandemic, we have witnessed a lack of medical goods like facemasks, personal protective equipment, ventilators, and some medicines, e.g., hydroxychloroquine. Some of these problems are caused by rules and policies, such as the policy to provide the antiviral hydroxychloroquine to only a few patients, since lupus and arthritis patients need it too, creating a shortage.[50] Another problem is the prevention of medical solutions resulting from prohibitive patents. An example is the inability to produce ventilators – which are urgently needed by some COVID-19 victims – because the original invention is protected by a valid patent. Thus, we have witnessed patent laws and legal systems causing a clash with the obligations of *availability* and *accessibility*. One example to learn from is provided by Medtronic and AmboVent, which shared their patented ventilator design without the need for manufacturers to pay for licenses via the issuing of special permissive licenses for the purpose of addressing the needs during the COVID-19 pandemic.[51] A similar problem arises when vaccines or antivirals with patent protection are ready to market. The US pharmaceutical company Moderna Inc. announced in October 2020 that it would not enforce patent rights in relation to its coronavirus vaccine during the pandemic.[52] However, the efforts of one company are not enough. The vaccine availability problem persists. How long will the delay in producing vaccines be allowed while lives are being lost? Should patents be allowed for such medicinal products during pandemics or should there be patent exceptions? The solution is not to depend on pharmaceutical companies to change their patent policies during pandemics, which would mean relying on private decisions. A responsibility also lies on governments and policymakers. There is a need to be legally proactive by learning from current needs and previous pandemics in order to design and implement legal provisions or system that are ready to invoke when pandemics strike.

4. PATENTS, PRICING, AND CLASH WITH THE RIGHT OF "ACCESS TO MEDICINE"

In the following, the focus is on the legal obligation of *accessibility* and its relation to the increased medicine pricing caused by patents. Tackling this requires application of some aspects of the *methodology of law and economics*. Based on Article 4 ICESCR and some national EU laws (e.g., German law), if a state cannot not fulfil its positive duty of protecting a human right, it can be construed as allowing other regimes to impair those fundamental rights.[53] This legal issue is relevant to patents from the economic viewpoint, since states must guarantee the economic *accessibility* of medicine. It translates to ensuring affordable medicines. The European Court of Human Rights (ECtHR) questions whether the balance between the public interest and the individual's interest is unfairly shifted.[54] To fully analyze this point, one would need study it on two planes: a theoretical economic dimension and an empirical dimension. This work does not indulge in mathematical analysis, but rather looks at the price levels from an economic viewpoint relating to interactions with law.

The usual claim to justify patent protection with higher prices is articulated by the aim of creating an incentive for inventors to keep conducting pharmaceutical research, without which many medicinal products would not be *available*. This justification creates a direct relation between legal patent protection and the first IHRL obligation of *availability*. However, the problem is that it goes against the second obligation of *accessibility*. The aim of IHRL instruments is to not separate the four obligations.

During pandemics like HIV/AIDS, pricing is critical.[55] The antiretrovirals are *available*, but the pricing policies hinder *accessibility* for many. The analysis of pricing requires a look at economic theory, to examine competition, the supply/demand curve, monopolies, and the governmental ability to support payments for medicines.[56]

In any business, the pricing process is one of the final steps before launching a product. It is affected by many factors, e.g., supplied volume, number of customers, and market price. Pharmaceutical companies do not have complete influence over pricing, but sometimes have partial leverage. If a medicine is priced very highly, it will be hard to sell, since many patients cannot afford it. Hence, it will not bring the desired revenue due to fewer customers. On the other hand, if the price of a medicine is too low, it would not be profitable, no matter how many units are sold. Therefore, pharmaceutical industries play the game of balancing two factors: making a good profit, while ensuring patients can afford the medicine. Doing so at a global scale, with huge differences between the purchasing powers of nations and patients, has a very slim chance of success for drugs with high R&D costs. At the same time, the price is affected by the level of supply and demand. Legally, patent laws empower the patent owner to prevent others from producing, marketing, using, selling, and importing the patented medicinal product. For instance, Article 28 in Section 5 "Patents" of TRIPS[57] states:

TRIPS Article 28 - Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. (...)

With such rights, the patent owner can create a monopoly that allows them to choose whether to produce large quantities of the medicine at a lower price or smaller quantities at a higher price. Since it is a business for profit, a pharmaceutical company will select the market price promising the largest profit. Clearly, this market reasoning does not take into consideration the right of "access to medicine" and the ability of patients to purchase the medicine. Another legal problem that needs revisiting is the negligence of the right of every human being to enjoy scientific benefits. Article 15(1)(b) ICESCR recognizes the right of everyone "to enjoy the benefits of scientific progress and its applications."[58] UDHR Article 27(2) articulates "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."[59] However, those rights have – thus far – been neglected. An important issue is that the UN Member States, CESCR committee, and the UN (General Assembly and Human Rights Council and its Special Rapporteurs) have not yet emphasized this as a human right,[60] although it is clearly written to be interpreted as such. Another alarming issue is that the *travaux préparatoires* are taciturn on the UDHR provision.[61] From an empirical economic approach, prices for generic medicines are much lower than those for branded ones. In the USA, the price of the first generic is around 60% of the branded medicine. It falls to 17% when twenty generics have entered the market.[62] From a legal perspective, CL come into play in this economics and law interaction. The UK has practiced invoking CL. Canada also has a quite long experience of CL. The experiences of these two countries confirm the previous findings on pricing.[63] Not only does this economic analysis indicate that patent regimes affect the price of medicine, but there is also strong evidence supporting this. For instance, in situations when governments face pandemics, they threaten patent protection by imposing CL. This helps achieve large reductions on drug prices. Further evidence is found in the Brazil HIV/AIDS program to produce drugs locally, where a 70% price reduction was achieved during a period of the high demand in 2001.[64]

46 Moeckli (n 39) 196.
47 Ibid.
48 See p 10 in ICESCR (n 36) United Nations International Covenant on Economic, Social and Cultural Rights, United Kingdom, British Overseas Territories, Crown Dependencies 6th periodic report (2016).
49 Moeckli (n 39) para 43.
50 Elizabeth Cohen and Marshall Cohen, "After Trump's statements about hydroxychloroquine, lupus and arthritis patients face drug shortage," (7 April 2020) CNN Health https://edition.cnn.com/2020/04/07/health/hydroxychloroquine-shortage-lupus-arthritis/index.html accessed 7 April 2020.
51 Darrell Etherington, "Medtronic is sharing its portable ventilator design specifications and code for free to all," (30 March 2019) TC Verison Media https://techcrunch.com/2020/03/30/medtronic-is-sharing-its-portable-ventilator-design-specifications-and-code-for-free-to-all/ accessed 30 March 2020; Robert L. Read, "The Open Source Ventilator Game Has Changed: AmboVent and Medtronic COVID-19 Ventilators Open Sourced," (1 April 2020) Medium https://medium.com/@RobertLeeRead/the-open-source-ventilator-game-has-changed-ambovent-and-medtronic-covid-19-ventilators-open-d645bde594cc accessed 2 April 2020.
52 Moderna Inc. "Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic" Press Release (Moderna 8 October 2020) https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19 accessed 7 March 2021.
53 ICESCR (n 36) art 4; German law HD Jarass and B Pieroth, Grundgesetz für die Bundesrepublik Deutschland. Kommentar (ed 7, 2004) Vorb vor Art 1 para 24.
54 Mark P. Villiger, Handbuch der Europäischen Menschenrechtskonvention, 2nd ed (EMRK 1999) 344–345.
55 Holger Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine (OUP 2007) 148.
56 Ibid. 138–151.
57 WTO (n 7) Art 28.
58 ICESCR (n 36) Art 15(1)(b).
59 UNGA (n 34) Art 27(2).
60 UN, Report of the High Commissioner for Human Rights, Economic, Social and Cultural Rights, The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights (UN, 27 June 2001) UN Doc E/CN.4/Sub.2/2001/13, para 10 ff.
61 Hestermeyer (n 55) 143–144.
62 Jerry Stanton, "Comment: Lesson for the United States from Foreign Price Controls on Pharmaceuticals" (2000) 16 Conn J Int'l L 149, 158.
63 Fredric M. Scherer, "The Economic Effects of Compulsory Patent Licensing" in Ruth Towse and Rudi Holzhauer (eds), The Economics of Intellectual Property: Patents (Edward Elgar 2002) 315, 350.
64 Anne-Christine D'Adesky, Moving Mountains, The Race to Treat Global AIDS (Verso 2004) 28.

5. ANALYSIS OF THE CONFLICT

After analyzing the links between patent pricing and the legal conflict, I will revert to the dogmatic method by examining the applicable laws highest up in the hierarchy, namely treaties and legislations, and how they have been used in practice. Then, I will move on to case law.

5.1. Provisions

TRIPS is the most comprehensive agreement on IP rights (IPR). Not only does it harmonize patent rules in Member States, but it also provides a minimum standard for protection. In the EU, patent rights are the least harmonized of the IPR. In addition, the Court of Justice of the European Union (CJEU) has adopted a restrained approach in patent discipline.[65] This is particularly true in the CJEU case law on patent protection and where TRIPS is an applicable instrument.[66] After ratification of the Lisbon Treaty,[67] introducing Article 207 of the Treaty on the Functioning of the European Union (TFEU)[68] on "Common Commercial Policy," the CJEU took a clear stance on including TRIPS in its judgments as a harmonizing legal instrument for the patent system in the EU. *In the case of Daiichi Sankyo Co. Ltd and Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon,*[69] the CJEU mentioned that common commercial policy also concerned the commercial aspects of IP and that if the EU was intended to promote international trade, this fell within common commercial policy.[70] Regarding TRIPS, the CJEU noted that:

> *[Its] primary objective is to strengthen and harmonize the protection of intellectual property on a worldwide scale [and that] of reducing distortions of international trade by ensuring, in the territory of each member of the WTO, the effective and adequate protection of intellectual property rights (…) [it] contributes to attaining that objective by setting out, for each of the principal categories of intellectual property rights, rules which must be applied by every member of the WTO.*[71]

In this respect, Section 5 of TRIPS (Articles 27–34) can be used to protect aspects of patents with specific power endowed in Article 28. Looking again at the interference with human rights instruments, Article 15(1) ICESCR and Article 27 UDHR were used a few years ago to try to justify patent collisions with the right of "access to medicine."[72] Thus, not only patent laws can be used to protect pharmaceutical patents, but also human rights laws. However, one cannot have high expectations on their use nowadays. They protect the moral and material interests of authors, but do not coexist with patents.[73] These articles do not protect patents as such, nor do they protect pharmaceutical companies. Article 15 ICESCR tries to strike a balance between protection of the interest of the inventor and public access to the invention. Usually, the practice is to protect the inventor's interests first. However, in cases when the right "to health" is seriously threatened, there would be greater support for protecting public access to pharmaceutical technologies and patents. Article 15(1)(c) ICESCR does not justify the interference of patent laws with the right of "access to medicine." Moreover, patent owners often base their claims on regional instruments. For instance, in the EU, inventors depend on the Charter of Fundamental Rights of the European Union, and in the USA, they rely on the American Declaration of the Rights and Duties of Man. These instruments protect IP interests as property.

In the context of pandemics, if they are considered to be emergencies, another legal instrument to examine is the ICCPR, because it allows derogations in emergencies that threaten lives in a nation. The most relevant provisions are found in Article 4 ICCPR (below). An interesting issue is that it contains limitation clauses, so Member States can limit the right in compliance with the clauses and the principle of proportionality (which I analyze in the discussion on balancing rights in subsection 9.4). By utilizing this option in the ICCPR, Member States' interference with the right can be justified.[74]

[65] Francesca Venerucci, A Comparative Study of the CJEU and ECtHR Approaches on Intellectual Property: Unity or Division? (thesis, UNIBOCCONI 2016) 72.
[66] Ibid.
[67] Treaty of Lisbon, EU (2007/C 306/01).
[68] TFEU (Treaty on the Functioning of the European Union) (entered into force on 1 December 2009) Part 5 Art 207 (e.g., Article 133 TEC).
[69] Daiichi Sankyo Co. Ltd and Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon (Case C-414/11) EU:C:2013:520 Judgment CJEU (Grand Chamber 18 July 2013).
[70] Ibid. paras 45–48.
[71] Ibid. para 58.
[72] Werner Meng, "GATT and Intellectual Property Rights - The International Law Framework" in Giorgio Sacerdoti (ed), Liberalization of Services and Intellectual Property in the Uruguay Round of GATT (Proceedings of the Conference on The Uruguay Round of GATT and the Improvement of the Legal Framework of Trade in Services, Bergamo 21–23 September 1989, published 1990) 57, 68.
[73] Hestermeyer (n 55) 152–153.
[74] Manfred Nowak, Introduction to the International Human Rights Regime (RWI 2003) 56.
[75] Hestermeyer (n 55) 152.
[76] ICCPR (n 2) Art 6.
[77] WHO (n 27); Worldometer, "Coronavirus" https://www.worldometers.info/coronavirus/ accessed 19 May 2020.
[78] WHO, Summary (Rolling updates on coronavirus disease, COVID-19, 17 May 2020) https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen accessed 19 May 2020.
[79] Elizabeth Cohen, "Early results from Moderna coronavirus vaccine trial show participants developed antibodies against the virus" (18 May 2020) CNN Health https://edition.cnn.com/2020/05/18/health/coronavirus-vaccine-moderna-early-results/index.html accessed 18 May 2020.
[80] WHO, "Accelerating a safe and effective COVID-19 vaccine" (UN) https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/accelerating-a-safe-and-effective-covid-19-vaccine accessed 29 April 2020.
[81] James Love, Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord (UNDP, 2001) para 8.
[82] Zachary Brennan, "EMA and FDA Historically Agree on Just About Every New Drug Approval, but is That Slowly Changing?" (16 August 2019) Regulatory Focus.

ICCPR Article 4

1. In time of public emergency which threatens the life of the nation and the existence of which is officially proclaimed, the States Parties to the present Covenant may take measures derogating from their obligations under the present Covenant to the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with their other obligations under international law and do not involve discrimination solely on the ground of race, col our, sex, language, religion or social origin.

2. No derogation from articles 6, 7, 8 (paragraphs 1 and 2), 11, 15, 16 and 18 may be made under this provision. (…).

This sends us back to ICESCR Article 4 to check the limitation obligation; some interpretations would justify interference.

ICESCR Article 4

The States Parties to the present Covenant recognize that, in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.

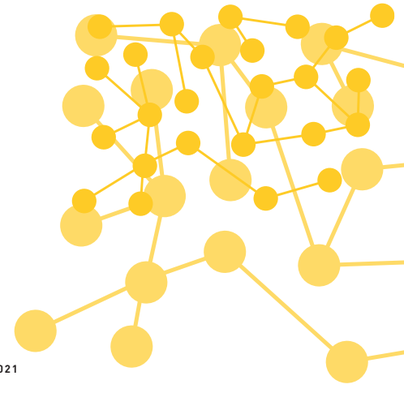
A word-by-word analysis of this article does not find reference to emergencies or survival (life-threatening issues). However, some have found justification through interpretation.[75] Furthermore, Article 6(1) ICCPR states the obligation to protect the right "to life" by law:

1. Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life. (…).[76]

However, other Article 6 provisions ((2)–(6)) make it obvious that this relates to death penalty regulations, refusal of authorization of genocide, and abolition of capital punishment. These life-threatening issues are specifically mentioned in the provisions of the article, but no other conditions related to life are listed. The question is whether Article 6(1) ICCPR can be used to protect the right "to lifesaving medicine." Does not the right "to life" include the right "to lifesaving" products? One can argue for or against this; however, the following analysis shows that there is a right to lifesaving medicine. The problem is that the right "to life" is not explained or further articulated in specific detail. It is left to judges to interpret it and decide to place on governments an *obligation* of *accessibility* "to lifesaving medicine." Going back to the interpretation, the article clearly states the legal obligation to protect the "inherent right to life." The rest of the article gives three instances of such protection (listed above), but does not limit the previous statement, since there is no phrase or wording indicating that the "right to life" is exhausted by those three instances. By deduction, the first two sentences encompass all instances of the right to protection of human life. This right relates to the obligation of a Member State to not end a life and to provide products that aid in decreasing or eliminating a threat of death. The relevant medical/medicinal products would include inter alia ventilators, pacemakers, and lifesaving medicine (e.g., HIV/AIDS antiretrovirals and COVID-19 vaccines).

In all these instruments, the right "to life" does not contain a limitation clause related to patent law. Most human rights articles can be limited under certain conditions. This means that a negative overlap – like that which patent law has with the right to "access to medicine" – could be justified under human rights law. On the other hand, patents protect revenue for pharmaceutical companies, thus motivating creation of new medicinal solutions. From a legal perspective, such an argument is used to protect patent owners' rights, as they support access to future needed medicine. This can create controversy when epidemics or pandemics occur, since there will be a fight against time, to save lives. A proof of this concept is evident in the current struggle to limit the number of deaths and infections from the COVID-19 outbreak.[77] The WHO declared the coronavirus outbreak a pandemic in February 2020.[78] The question that we need to be proactive about is access to vaccines/antiviral medicine.[79] Such medicinal products have been tested before approval for release,[80] and such testing processes will continue for new versions against new virus strains. The conflict requires an economic balance between the availability of research financing for developing new medicines and the prices of said medicines.

The only way to protect the "incentive to invent" is via patent protection. If exceptions to patent validity are favored in some areas due to life-threatening diseases, the incentive to innovate is lost in the area where it is most needed. Moreover, there is criticism of patent systems in general (e.g., a study shows that only 54% of patents are judged as valid in courts) even for a strong patent office like that in the USA.[81] The argument that patents motivate innovation does not say anything about patent limits. It favors patent law beyond all boundaries and is taciturn on how much profit is sufficient to incentivize inventors. The European Medicines Agency (EMA) and US Food and Drug Administration (FDA) concur in their decisions to approve new drugs in more than 90% of cases, according to a new study from EMA and FDA officials who looked at 107 applications from 2014 to 2016.[82] No practical solution would be feasible without governments being involved. Hence, legal issues must be addressed by the policymakers and legal specialists in governments, e.g., the EU Parliament.



5.2. Case law

In the pharma sector, it is not possible to consider domestic norms only, since medicinal products are needed worldwide. Moreover, as pandemics are global disease outbreaks, the mindset for legal analysis must be in harmony with international issues. Patents, in addition to being protected by domestic laws, can be listed and explained in treaties as investments to be protected.

5.2.1. Case law without expropriation

In many cases, the conflict between IPR and human rights is evident without the need for a pharmaceutical company to file for compensation based on allegations of a state having practiced unlawful expropriation. When national markets are interconnected (e.g., in the EU), pricing on one national market can affect that on another because of parallel imports. Hence, a medicine placed on a low-price market by the patent owner may be imported by some other company into a more highly priced market. This affects the patent owner's profit prospects.

In relation to the price of medicine, a good case to learn from is *Hazel Tau et al. v. GlaxoSmithKline, Boehringer Ingelheim et al., Competition Commission*.[83] GlaxoSmithKline and Boehringer Ingelheim were charged with excessive pricing of antiretrovirals in violation of the competition law of the Republic of South Africa, when the international best price offer of the branded product was compared with the price of a WHO prequalified generic. The court found that the branded drug was priced around 230% higher than the generic. This case revealed two important issues. First, the price difference between branded medicine and generics can be questionably large. Second, an argument arises on whether some profit can be made by branded drugs if they lower the marginal difference compared with cheaper medicinal products. In pandemic times, would governmental institutions and international organizations be able to pay such prices for branded medicine or vaccines when the number of patients is very high? The cost would certainly overstretch healthcare budgets. Court decisions like that in this case may help in identifying a problem that needs attention: marginal price differences and the need for governmental interference to lower prices during pandemics. This calls for a set of emergency laws that can be invoked when a pandemic strikes.

In the *Bayer AG v. Commission of the European Communities*[84] case, monopolies threatened to limit the supply on the market with a lower price – to prevent a medicine from leaving the country – or to set a unitary high price to prevent a loss of sales in a higher-priced country. At the same time, many of these drugs would have never been invented if not for patents. From a political viewpoint, it is a fact that monopoly incomes due to TRIPS' strengthening of patent legislation are commonly (but not always) transferred from less developed to more developed countries. Such threats have been used in debates on exporting cheaper drugs from Canada to elderly citizens in the USA, though it is hard to see how their realization would prevent the exportation of medicinal products.[85] Bayer acted in this way when sales of a drug (Adalat) in France and Spain grew dramatically, because the medicine was exported, at a much higher price, to the UK. Because its product was under governmental price control, Bayer reacted by filling orders only to a level determined by the orders of previous years. This shows that governmental interference and court decisions can play a major role in controlling access to medicine.

[83] Hazel Tau et al. v. GlaxoSmithKline, Boehringer Ingelheim et al. (CC) Republic of South Africa, Statement of Complaint in Terms of Section 49B(2)(b) of the Competition Act 89 of 1998; See also Competition Commission (CC), Hazel Tau and Others v. GlaxoSmithKline and Boehringer Ingelheim: A Report on the Excessive Pricing Complaint to South Africa's Competition Commission (Republic of South Africa, 2003).

[84] Bayer AG v. Commission of the European Communities, (Case T-41/96) EU:T:2000:242 Judgment CJEU (26 October 2000).

[85] Hestermeyer (n 55) 160–181.

[86] WTO, Minutes of Meeting of the Council for TRIPS (27–28 October & 6 November 2009).

[87] AstraZeneca AB and AstraZeneca plc v. European Commission (T-321/05) EU:T:2010:266 Judgment CJEU (1 July 2010).

[88] AstraZeneca AB and AstraZeneca plc v. European Commission (C-457/10 P) EU:C:2012:770 Judgment CJEU (6 December 2012).

[89] "Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs" (15 June 2005) Press Release IP/05/737 Brussels 1.

[90] AstraZeneca (n 87) para 313.

[91] Ibid.

[92] Smith Kline & French Laboratories Ltd. v. the Netherlands (Decision No 12633/87) CE:ECHR:1990:1004DEC001263387 European Commission of Human Rights (4 October 1990).

[93] Ibid., see para 3 on p 8 in "AS TO THE ADMISSIBILITY OF Application No. 12633/87" http://hudoc.echr.coe.int/app/conversion/pdf/?library=ECHR&id=001-738&filename=001-738.pdf&TID=ihgdqbxnfi accessed 5 March 2021.

[94] Centrafarm BV v. Winthrop BV (C-16/74) EU:C:1974:115 Judgment CJEU, ECR 01183 (31 October 1974); Merck & Co. Inc., Merck Sharp & Dohme Ltd. and Merck Sharp & Dohme International Services BV v. Primecrown Ltd., Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd. and Beecham Group plc v. Europharm of Worthing Ltd. (Joined Cases C-267/95, C-268/95) EU:C:1996:468 Judgment CJEU, ECR I-06285 (5 December 1996); IHT Internationale Heiztechnik GmbH v. Ideal-Standard GmbH (Case C-9/93) EU:C:1994:261 Judgment CJEU, ECR I-02789 (22 June 1994); SA CNL-Sucal NV v. HAG GF AG (Case C-10/89) EU:C:1990:359 Judgment CJEU, ECR I-03711 (17 October 1990).

[95] Treaty establishing the European Community (Nice consolidated version) - Part Three: Community policies - Title I: Free movement of goods - Chapter 2: Prohibition of quantitative restrictions between the Member States - Article 28 - Article 30 - EC Treaty (Maastricht consolidated version) - Article 30 - EEC Treaty.

[96] EC "EU Member States sign an agreement for the termination of intra-EU bilateral investment treaties" (5 May 2020) Financial Stability, Financial Services and Capital Markets Union.

[97] Eli Lilly and Company v. Government of Canada, UNCITRAL, ICSID Case No UNCT/14/2, Award (16 March 2017).

[98] North American Free Trade Agreement (signed in 1992, entered into force on 1 January 1994) (NAFTA).

In the EU, there are interesting cases on seizures of generic medicines in transit[86] in the Netherlands and Germany, which were discussed by the TRIPS Council in 2009. On grounds of the Council Regulation (EC) No 1383/2003 of 22 July 2003 "concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights" the national customs officer in an EU Member State is given the task to protect – by police power – the IP laws on goods transiting through EU ports. This raises the issue of the doctrine of police powers. Using the powers bestowed on the custom personnel and based on unclear patent violation possibilities, the police initiated temporary seizures and delayed nearly 20 shipments of medicines in transit. The major issue was that the medicinal products were lifesaving (used to treat AIDS, Alzheimer's disease, heart conditions, and high blood pressure). The pharmaceutical corporations Sanofi-Aventis SA, Novartis AG, and Eli Lilly & Co requested that the shipments be detained. The Indian representative considered those actions "serious impediments to access to medicines" and a violation of core principles of the TRIPS Agreement. The case resulted in negotiations between the parties, where an understanding was reached with the EU over the pending complaint before the Dispute Settlement Body. The medicines were sent back to the source after months of delay. The case reveals a negative side to pharmaceutical patent owning in the EU.

Two cases, *AstraZeneca AB and AstraZeneca plc v. European Commission (Case T-321/05)*[87] and its appeal in *Case C-457/10 P*,[88] show how the CJEU has favored keeping medicine costs down and encouraging pharmaceutical innovation. AstraZeneca faced two charges: (i) misleading representation to the EU domestic patent offices, and (ii) an attempt to deregister the marketing authorizations for its drug (Losec) capsules in Sweden, Denmark and Norway and withdraw them from Scandinavia in order to launch another, similar drug (Losec MUPS tablets). The CJEU judged that AstraZeneca was to pay 60 million euros for misusing the patent system by unlawfully and in bad faith obtaining a Supplementary Protection Certificate (SPC) to block or delay generic competitors of Losec and keep its medicine price artificially high.[89] The judge stated that:

> *Patent protection is central to the encouragement of innovation in economically viable conditions and it is therefore necessary to recognise a public policy imperative that undertakings should not be unduly deterred from registering patents in the pharmaceutical sector under the SPC scheme.*[90]

An EU commissioner argued the following: (i) Support should be strong for patent protection of innovative products, so they get a satisfactory return on their R&D investment. However, the legislator should determine the length of the suitable protection period. (ii) Generic medicines "keep costs down [and] (...) competition from generic products after a patent has expired itself encourages innovation in pharmaceuticals."[91] The appeal case was dismissed by the CJEU, upholding the previous decision.

One interesting case of the ECtHR on the issue of CL is *Smith Kline & French Laboratories Ltd. v. the Netherlands*.[92] The dispute was about CL granted by the Netherlands Patent Office, where there were two dependent patents, each owned by a disputing company. The ECtHR considered such an act to be lawful and supported the legitimate purpose of encouraging technological and economic development. The interesting issue is that the ECtHR applied the *proportionality principle* (discussed in subsection 9.4) when deciding that "(...) the owner of the dominant patent is entitled to royalties in respect of each compulsory licence granted under the legislation and receives reciprocal rights under the dependent patent."[93] Hence, a balanced CL was granted; this could be used, by analogy, in many other cases. In the following CJEU cases, (1) *Centrafarm BV v. Winthrop BV, Merck & Co. Inc.,* (2) *Merck Sharp & Dohme Ltd. and Merck Sharp & Dohme International Services BV v. Primecrown Ltd., Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd.,* (3) *Beecham Group plc v. Europharm of Worthing Ltd.,* (4) *IHT Internationale Heiztechnik GmbH v. Ideal-Standard GmbH,* and (5) *SA CNL-Sucal NV v. HAG GF AG,*[94] the ECtHR prohibited EU Member States from banning parallel imports originating within the European Community under EC Treaty Articles 28 and 30.[95]

5.2.2 Case law under expropriation

Case law creates confusion in relation to when changes are made in domestic patent law and its interference with pharmaceutical patents granted before the patent law was changed (overlapping with access to medicine). This subsection investigates cases where such an act by a state was considered by pharmaceutical companies (defendants) tantamount to expropriation. Medicinal products are universal and pharmaceutical industries try to sell them on worldwide markets. Sometimes, this means that the pharmaceutical company is (legally speaking) to be considered an investor in a foreign state, with the patent registration in the foreign state being its foreign direct investment. Even within the EU, different Member States could be signatories of investment agreements. Although EU law functions as a supranational law for the EU States, such bilateral agreements cause controversy and debate. The EU government and CJEU have suggested cancelling such intra-EU agreements.[96]

An interesting case is *Eli Lilly and Company v. Government of Canada*[97] under the North American Free Trade Agreement (NAFTA),[98] where three Canadian courts (provincial, appeal, and supreme) made similar decisions. After having exhausted local remedies, Eli Lilly (a US pharmaceutical company) still wanted to file for an arbitration under NAFTA. Hence, there are four decisions, all with similar conclusions. Eli Lilly owned patents for the Zyprexa and Strattera drugs, which were registered in Canada before 1993. Until that year, the Canadian patent law allowed for CL. However, when Canada recognized TRIPS, the effect was large. Canada introduced the concept that an invention "must be useful" to grant a patent. Eli Lilly did not expect the new doctrine to take effect on existing patents. All courts invalidated the patents on

ground of not having a proof for the "must be useful" concept. Hence, the conflict was created by the intersection of three issues: (i) the investment agreement (NAFTA) protecting investment and patents in Chapters 11 and 17, respectively, (ii) the patent claims related to access to medicine, and (iii) the change in Canadian patent law while the patents were within their respective validity periods.

Accordingly, Novopharm (a Canadian pharmaceutical company) obtained regulatory approval to market a generic based on Zyprexa. Eli Lilly considered this retroactive effect of the court decisions on the previously granted patents as equivalent to an unlawful expropriation of its investment (the patent registration) in Canada on the grounds of the investment and patent definitions under NAFTA. Eli Lilly claimed that the court decisions were attributed to the Canadian State. The Canadian State (defendant) won all the cases, and the final tribunal decision took into consideration patent laws, the bilateral investment treaty (BIT), and human rights.

All the courts and the arbitration tribunal seemed to view patent law as the major applicable law, meaning that the changes were allowed. This raised a question regarding the three laws (patent law, BIT, and IHRL): whether or not they overlap in such cases. The courts, however, showed a mindset of considering the public interest. Comments mentioned keeping non-useful patents in Canada that would stop research in this field as the IPR could conflict with current and future research related to the right to health. For the sake of people's health and ordre public (better and faster research in healthcare products), the patents were invalidated on grounds of the new "usability" criteria. This case is applicable to pandemics in general, where any patent on a vaccine can hinder access to a new vaccine (timewise and research-wise). If there is a technical lack in "proving the usability of a patent," this should be corrected in a way where the courts have a chance to request amendment of the patent descriptions, without necessarily invalidating the patents. This case presented intriguing reasoning from judges on human rights within applicable laws.

In the judgment of the CJEU in *Daiichi Sankyo Co. Ltd and Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon*[99] on a similar issue regarding patents older than the Lisbon Treaty, the viewpoint of the CJEU was that:

> *[T]he TRIPs Agreement obliges members of the WTO to make it possible to obtain patents for inventions of pharmaceutical products. That obligation cannot, however, be understood as meaning that members of the WTO which, in a period anterior to the date of that agreement's entry into force, excluded protection of inventions of pharmaceutical products claimed in patents granted for inventions of processes of manufacture of those products must, from that date, regard those patents as covering those inventions of pharmaceutical products.*[100]

Regarding the EU pharmaceutical industry, two of the famous clashes are those of *Novartis AG (Switzerland) v. Union Of India* case and the events when Novartis threatened to go to arbitration against Colombia.[101] Novartis held patents in many countries, including India and Colombia, for Glivec, a drug used to treat cancer. In the first case, the Indian Supreme Court upheld the Indian Patents Act against Novartis' patents and allowed for "access to medicine" in an affordable manner. In the latter conflict (against Colombia), Novartis threatened to resort to international arbitration on the grounds of an alleged violation of the Swiss-Colombian BIT. The question again was whether States should invalidate such critical patents or allow CL in case of a conflict with patent laws or BITs. The WTO has stated that CL "is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself."[102] This is considered to create flexibility. Many countries allow for CL, but this issue was regulated under TRIPS, as discussed above in relation to the *Eli Lilly v. Canada* case.

Nonetheless, the type of disease and the relevant access to medicine is crucial to take into consideration when deciding on strong measures like CL. For instance, in the case of HIV/AIDS, millions of people were affected by the time the first HIV antiretrovirals were produced. Moreover, only one in a thousand of those patients had access to such antiretroviral medicines. More than eight thousand humans were dying of HIV/AIDS daily. Conflicts on HIV-related medical patents came after the adoption of TRIPS. Therefore, some nations revoked or invalidated patents and others reverted to CL in relation to the aforementioned decisions.

6. APPLICABLE LAWS AND HIERARCHY

The issue of the applicable laws to be considered by courts in such conflicts is complicated, because judges must decide which instruments are applicable and create a hierarchy based on the case at hand. First, regarding IHRL, it is within the powers of the court to neglect it, consider it as a fact, or leverage its value as the highest of legal instruments in the conflict. Second, the TRIPS Agreement could be part of the IP regime in a state. One possible way to better consider this applicable law is to view TRIPS within the conflict as falling partly within the IP regime and partly within the world trade regime. TRIPS is not only intended for patent protection, but it is one of the WTO agreements. Consequently, it falls under the rules of the WTO, which is – to a large part – concerned with trade. In the interaction with human rights, the WTO order (trade-based) intersects with the IHRL regime (moral-based). When a clash occurs, current practices show that the organization of hierarchy between the two is underdeveloped.[103]

7. STRENGTHS AND WEAKNESSES OF TRIPS AS A WTO AGREEMENT

The WTO regime has a strength in its reach, which has two causes: many states are members, and trade touches most aspects of life. However, this strength becomes a weakness in case of conflicting interests, because when the WTO touches upon other spaces, any other legal system becomes a potential colliding force, as many other systems affect trade. For instance, in the cases of seizure of generic medicines in transit[104] in EU ports, although the EU police doctrine (discussed in subsection 9.4) considered this act lawful, it did affect trade relations. Hence, trade rules and trade sanctions can touch on many aspects in many states.[105] How can pharmaceutical patents be enforced during wars or pandemics if IHRL requires fulfilment of the right to access medical goods in the best possible way? This involves ensuring speed and quality, without discrimination. Do we see this happening during the COVID-19 pandemic, among all the signatories to those two legal norms? Should not this pandemic lead to prioritization of IHRL over any other regime? The answer to the second question is yes, but how and to what extent?

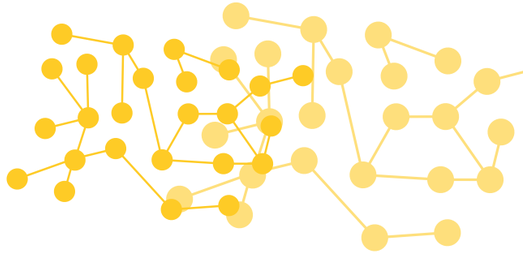
Although TRIPS obliges WTO Members to introduce patents, it allows them to make use of certain exceptions. As patents unjustifiably interfere with "access to medicine" during disasters and pandemics, nations and governments can only escape the violation of their IHRL obligations by invoking such exceptions. This flexibility of TRIPS is a strength for all parties. It generally does not provide for exclusion from patentability, but rather for a limitation of patent rights.

8. UNIFICATION OR REORGANIZATION OF REGIMES?

Unification of regimes refers to substantive uniformity, preventing conflicts between norms.[106] However, during pandemics, when we need quick decisions, it would not aid legislators or courts in faster and better understanding of the intersection of conflicting norms. The question then becomes if total divisibility (separation) of regimes, i.e., creation of special norms (lex specialis of IHRL and patent law) in the legal space would help. Total independence from the moral obligations of IHRL during pandemics would mean that only TRIPS applies. How do we reflect IHRL in legal decisions? IHRL must be considered as higher ranking, otherwise we would go against all the articles that protect the right to "life," "health," "access to medicine" and "prevent epidemics" (Article 11 European Social Charter).[107] For this reason, this paper proposes a reorganization of the overlapping laws in case of health emergencies and pandemics.

The proposed reorganization sheds light on the fact that TRIPS should not be considered to be only an IPR instrument, as it stems from a trade purpose (a WTO regime). Even in its protection of patents, TRIPS sets a minimum protection standard for invention owners (pharmaceutical companies) so that trade relations run more smoothly. Although TRIPS is used to harmonize EU patent legal systems, a large part of it is focused on trade. The proposed reorganization considers the trade part not intersecting (thus not conflicting) with IHRL and the right of "access to medicine." This does not mean that TRIPS and IHRL do not intersect at all. These two regimes intersect in the parts related to patents, i.e., Section 5 TRIPS (Articles 27–34).

Therefore, this paper considers the overlap with Section 5 TRIPS, where the most relevant point of intersection is Article 28 TRIPS, on patent protection. On the other hand, IHRL instruments intersect with this part of TRIPS in several parts: Article 4 ICESCR, Article 4 ICCPR, Article 6 ICCPR on protection of the right "to life," Article 15 ICESCR and Article 27 UDHR. If practitioners or courts focus on the aforementioned articles of TRIPS and IHRL instruments, a well-defined frame of intersection between the different laws would be constructed. This is a reorganization that includes placing the right of "access to medicine" as a human right of the highest rank when it comes to lifesaving medicine (vaccines, antivirals, and antiretrovirals) in pandemics. The case law discussed above, where claims of expropriation had been filed, shows us that the legal space would include bilateral agreements only when a patent is defined in such an agreement under the section relating to investment. This makes a pharmaceutical manufacturer that owns a patent an investor in the state where the patent is registered. In such cases, any bilateral treaty would become part of the reorganized legal space, in addition to all the aforementioned articles of TRIPS and IHRL. Although this model of thinking about the legal spaces shows a clear intersection of subsets (articles) of



[99] Daiichi Sankyo Co. Ltd and Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon (Case C-414/11) EU:C:2013:520 Judgment CJEU (Grand Chamber 18 July 2013).

[100] Ibid. para 82.

[101] Business and Human Rights Resource Centre, "Colombia: Leaked documents reveal Novartis threatened govt. with intl. investment arbitration over licensing of pharmaceutical patents" (12 Apr 2017) https://www.business-humanrights.org/en/latest-news/colombia-leaked-documents-reveal-novartis-threatened-govt-with-intl-investment-arbitration-over-licensing-of-pharmaceutical-patents/ accessed 3 March 2020; Public Eye, "Compulsory licensing in Colombia: Leaked documents show aggressive lobbying by Novartis" Press Release (11 April 2017).

[102] See, TRIPS and Health Frequently Asked Questions https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm#:~:text=What%20is%20compulsory%20licensing%3F,the%20patent%2Dprotected%20invention%20itself.

[103] Hestermeyer (n 55) 206.

[104] WTO (n 86).

[105] Steve Charnovitz S, "Trade Measures and the Design of International Regimes" in Steve Charnovitz (ed), Trade Law and Global Governance (Cameron May 2002) 27; David W. Leebron, "Linkages" (2002) 96 AJIL 5.

[106] Mario Prost, The Concept of Unity in Public International Law (Hart Publishing 2012) 46–48.

[107] ESC (n 44) Art 11.

legal instruments, it does not mean that there would always be conflicts within the intersecting areas. For instance, the UDHR instrument does not necessarily always interact with patent definitions in BITs. In this way, the proposed model can be in harmony with the practical reasoning in the aforementioned case law. This is because the case law took into account both regimes of trade and human rights. In this respect, the proposed reorganization does not mean that there is a unification with no conflicts between the rules, or that there is divisibility with prevention of conflict. Rather, it means that there are overlapping areas that could clash in some cases.

Regarding priorities (hierarchy), case law observation shows that each case has its own hierarchy. For instance, Article 11 ESC is lower in hierarchy than any article in ICESCR or ICCPR because they are higher-ranking international conventions. However, Article 11(3) ESC considers protection in cases of epidemics, which means a new look at this article should be considered. The next issue is whether this could work with the Biotechnology Directive[108] in the EU. The answer, based on case law of the CJEU, is negative. Hence, this reorganization model calls for a stronger EU patent law: a unified patent law. Since the value of human life should be of highest rank, the unified patent law should ensure that the hierarchy prioritizes human life over monetary goals while keeping patent protection relevant, to achieve a balance.

9. BALANCING PHARMACEUTICAL PATENTS AND MEDICINE ACCESSIBILITY

Without a balanced view on TRIPS/WTO and IHRL during pandemics, nothing significant would be achieved. Some previous work has been done in this regard, which is presented below. This previous work paves the way for possible recommendations. In this respect, this paper investigates relevant instruments, *inter alia* TRIPS and ICESCR.

9.1. TRIPS flexibilities

The TRIPS Agreement allows flexible measures to limit the rights of patent owners. The right of access to medicine is one argument among many in the flexibility interpretation.[109] For instance, one flexibility lies in Article 6 TRIPS, which covers patent exhaustion:

> *For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.*

Some courts interpret it as an "agreement to disagree," making each WTO member free to decide whether or not to observe the principle of international exhaustion of patents (in imports).[110]

Another flexibility is found in Article 30 TRIPS:

> *Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*

This article allows exceptions to patent protection. As the heading of TRIPS Article 31 ("Other Use Without Authorization of the Right Holder")[111] and its footnote explaining the meaning of the phrase "Other use"[112] indicate, the exceptions in Article 30 apply without the authorization of the patent owners. Accordingly, they can limit the effects of a patent monopoly, i.e., lower product (medicine) prices. The wording is not precise, but it paves the way for an entry point to use the right of "access to medicine."
The third point is in Article 27(1) TRIPS:

> *(…) patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*

Some states argue that the non-discrimination rule is subject to the exception of Article 30 TRIPS, thus establishing separate rules for pharmaceuticals.[113] The *travaux préparatoires* show that this non-discrimination rule was adopted to prevent automatic CL on pharmaceuticals and must be applicable to Article 31 TRIPS.[114]

The fourth point is TRIPS allowing revocation of patents via Article 32:

> *[A]n opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.*

Moreover, an important TRIPS flexibility is in Article 8 (below), allowing amendments to protect public health; hence, this adds a possibility to request amendments during a pandemic, to protect the obligation of "access to medicine":

TRIPS Article 8

Principles.

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

9.2. International Human Rights Law (IHRL) provisions

Article 15 ICESCR tries to strike a balance between the protection of the interest of the inventor and public access to the invention, as indicated by both Article 15(1)(a), (b) and paragraph 2 of that provision.[115] The problem is that this article has been made dormant, and a practical solution is needed to put it in use again.

9.3. Compulsory licenses (CL)

The most appealing legal solution for states to lower medicine prices is CL granted by domestic courts. CL do not require any consent from the pharmaceutical companies (patent owners). With CL, the court does not invalidate patents, as in the *Eli Lilly* case, but authorizes other parties to produce drugs, so the government can fulfil its obligation of accessibility. The CL solution is threefold as it: (1) safeguards access to medicine; (2) promotes local competition, and (3) supports local industry.[116] The states that were for or against CL relied on TRIPS Article 31 and Article 31bis:[117]

TRIPS Article 31

According to this Article[118] (…) the following shall be respected:
(a) authorization of such use shall be considered on its individual merits;
(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. (…)
(c) the scope and duration of such use shall be limited to the purpose for which it was authorized (…)
(d) such use shall be non-exclusive;
(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. (…)
(…)
(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
(…)
(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.
(…).

TRIPS was amended on 23 January 2017 by adding Article 31bis, an Annex and an Appendix. The amendments provided a legal basis for a WTO Member State to grant exclusive CL for producing generic medicines as well as for exporting them to other WTO Member States, which do not have the possibility to purchase the branded medicine or produce them locally.

When a measure is not justifiable under Article 30 TRIPS, it is checked through Article 31.[119] Nonetheless, most patent laws in industrial states (including the USA) include provisions to grant CL. Courts have granted CL in antitrust cases.[120] In some cases, CL push the pharmaceutical patent owners (companies) to lower their branded drug price.[121] Some researchers state that CL may only be granted in cases of patent abuse by the company, based on Article 5A(2) of the Paris Convention.[122] This is applicable via Article 2(1) TRIPS permitting members to grant CL to "prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent."[123] Moreover, Article 8(1) TRIPS (see above) requires members to show that CL are necessary for *ordre public*.[124] Even though CL lower drug prices, they have some weaknesses since they may discourage pharmaceutical companies from operating in a certain region or push them to find other ways (politically) to fix their prices. During the COVID-19 pandemic, if states were to inform pharmaceutical companies of a governmental will to grant CL, those companies would – most probably – stop their vaccine R&D programs. Hence, CL are not an optimal long-term solution during pandemics.

[108] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (6 July 1998).
[109] Hestermeyer (n 55) 229 ff.
[110] See Mag Instrument Inc. v. California Trading Company Norway, Ulsteen (Case E-2/97) E1997P0002 EFTA (3 December 1997) and Bundesgericht (Switzerland), Kodak SA v. Jumbo-Markt AG, 31 IIC 1018, 1022 (2000).
[111] See Heading of Article 31 TRIPS which states, "Where the law of a Member allows for other use(7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:" The reference to footnote 7 in this heading is explained in footnote 112, below.
[112] See footnote 7 in Section 5, Part II ("Standards concerning the availability, scope and use of Intellectual Property Rights") of TRIPS stating that "'Other use' refers to use other than that allowed under Article 30 [of TRIPS]."
[113] Hestermeyer (n 55) 237–238.
[114] Ibid.
[115] Committee on Economic, Social and Cultural Rights, General Comment No 17, para 2; Peter Drahos, "The Universality of Intellectual Property Rights: Origins and Development" in WIPO (ed), Intellectual Property and Human Rights (Panel Discussion to commemorate the 50th Anniversary of the Universal Declaration of Human Rights, Geneva, November 9, 1998, published 1999) 24.
[116] Hestermeyer (n 55) 239 ff.
[117] WTO (n 7) art 31bis of the TRIPS Agreement as amended on 23 January 2017.
[118] Heading (n 111).
[119] Contra D Gervais, The TRIPS Agreement. Drafting History and Analysis (2nd ed 2003).
[120] F-K Beier, "Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law" (1999) 30 IIC 251, 259–260.
[121] Ibid. 260.
[122] Paris Convention for the Protection of Industrial Property, 21 UST 1583, 828 UNTS 305 art 5A(2).
[123] Richard P. Rozek and Renee L. Rainey, "Broad-Based Compulsory Licensing of Pharmaceutical Technologies. Unsound Public Policy" (2001) 4 J World Intell Prop 459, 468.
[124] ER Gold and DK Lam, "Balancing Trade in Patents- Public Non-Commercial Use and Compulsory Licensing" (2003) 6 J World Intell Prop 5, 22–23.

9.4. Principle of proportionality

The proportionality principle was initiated as an idea in Aristotle's Nicomachean Ethics (Book V): to serve human good and be just, by applying the right ratio. It evolved to the concept of balancing interests and became a general principle of law. In patent law, it aids in striking a balance by finding the relationship between the end result and the means to reach it. The principle aids conflict resolution by balancing public interest arguments with the rights of the patent owners (e.g., pharmaceutical companies). It "demands there should be a reasonable relationship of proportionality between the means employed and the aim sought to be realized."[125] To apply this principle, three procedures need to be executed.[126] First, courts need to evaluate if a measure was suitable for its aim. The judges should check if there was a logical and acceptable link between what one party did and what its final goal was e.g., access to medicine. The second procedure is the evaluation of whether or not the goal could have been achieved with a less intense measure. The third and final procedure is the actual evaluation of the proportionality (balance estimate) between the measure and the benefit sought. Good examples include the two cases of *Azurix Corp. v. The Argentine Republic*[127] and *Biwater Gauff (Tanzania) LTD. v. United Republic of Tanzania*,[128] where the judges cited the ECtHR regarding the need for a reasonable relationship between the burden imposed on a foreign investor and the interest that the enforcement measures intended to achieve. Although this principle was applied by the ECtHR, its use causes confusion due to the practical difficulty of balancing the private interests of pharmaceutical companies against public interests.

9.5. Exception clauses

The use of exception clauses is an idea borrowed from the trade law instrument GATT.[129] Unfortunately, it does not refer to human rights, since it prioritizes business. Exception clauses may aid in achieving a balance between patent law and human rights by clearly explaining when a state can take exceptional regulatory measures to protect its public interest during pandemics without being held responsible for affecting the interests of pharmaceutical companies. It adds a maneuvering flexibility, which is crucial in cases of threats of legal obligations in relation to the right of "access to medicine." Nonetheless, there is not a wide implementation of exception clauses. Norway, Canada, and the USA include clearly articulated exception clauses in their agreement models. They mention that nothing in the agreement shall be construed as preventing a party from adopting measures "necessary to protect human, animal or plant life or health."[130] Such exception clauses achieve a kind of balance between the private interests of pharmaceutical industries and the public interest in the right of "access to medicine."

9.6. Doctrine of police powers

In this doctrine, police powers are viewed as "[t]he powers granted by the Constitution of the State in order to govern, establish, adopt as well as enforce laws that are designed for the protection as well as preservation of the public health."[131] Health officials may use police powers to enforce a treatment and prevent a specific healthcare conduct.[132] Much like in the case of exception clauses, Canada and the USA have models that include clauses to allow for the police power doctrine to be considered and used in favor of the state. This doctrine is as useful as the exception clauses, but its application has been limited to a few cases.

9.7. Corporate responsibility

Pharmaceutical companies have a responsibility to people. Under the current critical need for a COVID-19 vaccine, the right of "access to medicine" cannot be achieved if the business/investor only sees monetary dimensions, without giving regard to the human side. Patients and governments would face a huge problem. There is still debate on whether a business can bear responsibilities like humans do. According to UN representatives, it does not seem that the international human rights instruments discussed here currently impose direct legal responsibilities on corporations.[133] However, in life-critical matters, they should bear responsibilities. The important issue is for courts to see this point too. The OECD Guidelines for Multinational Enterprises have "recommendations addressed by governments to multinational enterprises [and] provide voluntary principles and standards for responsible business conduct consistent with applicable laws."[134] As a solution to this problem, this paper recommends clearer clauses for an obligation on pharmaceutical companies to give away the secrets to vaccines/antivirals in the case of a pandemic. Further, the clauses could state that after the pandemic, the company that revealed the secret would be granted a right to seek monetary compensation from states and specific organizations like the WHO and others. This issue – how pharmaceutical companies (as patent owners) could be given a monetary kickback after a pandemic – needs attention before the next COVID-19 vaccine/antiviral is ready to market and before another virus outbreak occurs.

9.8. Pricing vs. R&D

The crux of the matter lies in the high prices relative to the financial conditions of the patient (e.g., within the USA, the EU, and other countries). During pandemics, the cost for giving the vaccine to all the citizens at once can be higher than a budget may allow. If the R&D phase of pharmaceuticals (5–10 years, with hundreds of million EUR/USD being invested) is supported by large governmental budgets with clear legal provisions to protect pharmaceutical companies' interests and patients' lives, this can sooth the pandemic conflict. If not, imposing CL or obliging pharmaceutical companies to give away the secrets of their inventions (medicines) for free may shut down R&D entirely. Thus, the problems reside in the costs. If the costs of R&D in pharmaceutical industries are lowered with the help of governments and the WHO, the medicine prices can and would be lowered. Tackling this business issue is not easy – but it is feasible, especially with the strong interest and will created by a pandemic. Therefore, this paper suggests adding provisions that clearly require states to invest in pharmaceutical industries during pandemics. New laws could make this an obligation, rather than a recommendation. This calls for international institutions to help creating or phrasing such new provisions to control prices and ensure access to vaccines against COVID-19 and in future pandemics.

10. PROBLEM IDENTIFICATION

Identifying problems that need attention is crucial before trying to find solutions. The first problem identified was in the justification used by pharmaceutical companies regarding the aim of patents. They indicate that highly priced medicine is the largest incentive for inventors to keep conducting pharmaceutical research, without which many medicinal products would not be *available*. Thus, high prices serve to satisfy the obligation of *availability* of medicine. The problem is that they go against the second obligation, that of *accessibility*. This issue needs to be addressed by judges and practitioners, and attention to this is needed on the part of governments, the EU, the WTO, and related organizations.

The *second problem* that needs revisiting is the *negligence* of the right recognized in Article 15(1)(b) ICESCR for everyone "To enjoy the benefits of scientific progress and its applications." This right has been dormant and not used for decades, and this problem requires attention to this, to support "access to medicine."

The *third problem* relates to *the divisibility* of laws in many cases, where the intersection between patent laws and IHRL instruments is not fully studied. There is a need to attend to this problem, perhaps through the reorganization discussed in section 8. It would promote an understanding of where to look for provisions in case of such conflicts. The proposal considers the intersection of the two regimes in a number of articles, outside the trade issues in WTO/TRIPS. Hence, practitioners and courts should focus on: (i) Section 5 TRIPS (Articles 27–34), with significant regard to Article 28 and (ii) a few IHRL instrument articles, namely Article 15(1) ICESCR with Article 27 UDHR, Article 2 ECHR (based on Article 11 of the ESC), Article 4 ICCPR on limitation clauses, Article 4 ICESCR, and Article 6 ICCPR protecting the right "to life" by law.

In addition to identifying problems, this section presents recommendations based on: (i) previous work discussed in this paper and (ii) new ideas. Before reading the recommendations, it is advisable to study the decisions made by the CJEU regarding copyright in relation to human rights, so as to understand – by analogy – how to strike a balance. The three CJEU cases are: *Funke Medien NRW GmbH v. Federal Republic of Germany,*[135] *Pelham GmbH, Moses Pelham, Martin Haas v. Ralf Hütter, Florian Schneider-Esleben,*[136] and *Spiegel Online GmbH v. Volker Beck*.[137] These cases had a common issue; they required the CJEU to balance between IPR (copyright) and fundamental rights. By analogy, this research relates to the balance between IPR (patents) and human rights. In the aforementioned three cases, the CJEU stated that the EU Charter of Fundamental Rights contains rights corresponding to those guaranteed by the ECHR. Moreover, Article 52(3) of the Charter seeks to ensure consistency between the rights contained therein and those guaranteed by the ECHR, without affecting the autonomy of EU law or the CJEU. The difference here is that with regard to patents, we have only the Biotechnology Directive, which is not very clear on the issue of the right of "access to medicine." However, we can – by analogy – try to give recommendations that do not harm either side of the balance and respect the autonomy of EU law.

[125] EDF Services Limited v. Romania, ICSID Case No ARB/05/13 Award (2009) 293.

[126] M Andenas and S Zleptnig, "Proportionality: WTO Law: In Comparative Perspective," Texas International Law Journal, vol 42, No 3 (2007) 371–427; N Diebold, Non-discrimination in International Trade in Services: 'Likeness' in WTO/GATS, (Cambridge University Press 2010).

[127] Azurix Corp. v. The Argentine Republic, ICSID Case No ARB/01/12, Award (English) (14 July 2006).

[128] Biwater Gauff (Tanzania) LTD. v. United Republic of Tanzania, ICSID Case No ARB/05/22, Award (24 July 2008).

[129] General Agreement on Tariffs and Trade (1994) ("GATT").

[130] Ibid. Art XX(b).

[131] The Law Dictionary, "Police Powers" https://thelawdictionary.org/police-power accessed 1 June 2019.

[132] UNAIDS (Joint United Nations Program on HIV/AIDS) Criminal law, public health and HIV transmission: a policy options paper, Geneva, Switzerland (UNAIDS 2002).

[133] See John Gerard Ruggie, Business and Human Rights: Mapping International Standards of Responsibility and Accountability for Corporate Acts (OCHR, 2007) UN Document A/HRC/4/035 para 20.

[134] OECD, Guidelines for Multinational Enterprises (OECD, 2000) Preface, para 1.

[135] Funke Medien NRW GmbH v. Federal Republic of Germany (Case C-469/17) EU:C:2019:623 Judgment CJEU (29 July 2019).

[136] Pelham GmbH, Moses Pelham, Martin Haas v. Ralf Hütter, Florian Schneider-Esleben (Case C-476/17) EU:C:2019:624 Judgment CJEU (29 July 2019).

[137] Spiegel Online GmbH v. Volker Beck (Case C-516/17) EU:C:2019:625 Judgment CJEU (29 July 2019).

11. RECOMMENDATIONS

This research adopts some previous solutions, adds some relevant recommendations, and also puts forward some new ideas as recommendations.

First, this work adopts use of the available TRIPS flexibilities from the patent law side and Article 15 ICESCR from the IHRL side.

Second, it adopts the principle of proportionality and recommends its use by practitioners. However, this principle needs leveraging in its practical use, enlisting the help of law experts and economists to formulate a benchmark method.

Third, this work adopts the solution of exception clauses and proposes that the EU parliament, governments, and the WTO create legal templates with specific and clear clauses for protecting the human right of "access to medicine" without threatening states of being accused of expropriation.

Fourth, it adopts the principle of police powers of states when protecting the right of "access to medicine," especially in critical situations like pandemics. However, the recommendation is made to add clearer clauses to limit these powers.

It is worth mentioning that regarding CL and pricing, this work does not entirely adopt this solution, since many issues remain hard to settle and are case-dependent. Although patent revocation is more difficult than CL, CL are tough on pharmaceutical companies, which can invest hundreds of millions of dollars in R&D (as has been the case during the COVID-19 pandemic).

The second set of recommendations stems from new ideas identified through this research and requires the attention of governments (including the EU), financial institutions (including the European Investment Bank), the WHO, the WTO, and pharmaceutical companies.

Fifth, this paper recommends a reorganization of laws, as discussed in section 8, especially during pandemic times. The current state of defragmentation clearly indicates which provisions must be looked at when there is a clash between patent laws and the right to "access to medicine." Doing so proactively could streamline solutions. We cannot expect to solve the problems of pandemics in real time. Pharmaceutical industries invest huge amounts of money to develop vaccines, with the incentive of large ROI, and humans need vaccines. To balance such issues, R&D costs must be lowered for pharmaceutical companies – but not by threatening with CL. Hence, governments (including the EU), the WHO, and other organizations must compensate pharmaceutical businesses. To do so, legal rules must be in place before a pandemic occurs. We cannot afford creating real-time solutions by legislating during a crisis. This calls for creating legislations and provisions to be used in case of a pandemic, i.e., provisions specifically made for pandemics. This could include amending TRIPS by invoking its Article 8(1) to reformulate or add provisions based on the public interest and need. In this respect, the recommendation is to include clauses for protecting the human right to "access to medicine," which could be invoked during pandemics. Examples of such amendments have occurred within the WTO: the Doha Declaration, the South Africa pharmaceutical trial, and the decision in 2005 to amend TRIPS.[138] This investigation also recommends adding WTO provisions to invest in pharmaceutical R&D departments at lower prices. Many states have affirmed commitments to including human rights in WTO instruments, but nothing has materialized. This paper recommends making use of the COVID-19 pandemic as a driver to make legislation – because it is currently up to judges' interpretations to oblige pharmaceutical companies or governments to fulfill their legal obligation of "access to medicine."

Sixth is a recommendation related to clauses for *exceptions on patents*. This has been discussed in many IP circles since the COVID-19 outbreak. The paper recommends a provision related to pharmaceutical companies on patent exceptions (to be invoked in pandemic outbreaks only): (i) having R&D funded by governments (including the EU), the EU Investment Bank, and/or IP finance organizations, with a clear limit on how much the business can profit (to control drug prices) and (ii) being granted IPRs as special patent rights only *after* the pandemic. In the EU, we have recently witnessed a budget proposal from the Commission (Horizon Europe) that should "scale up the research effort for challenges such as the coronavirus pandemic, the extension of clinical trials, innovative protective measures, virology, vaccines, treatments and diagnostics, and the translation of research findings into public health policy measures."[139] Moreover, the EC (on 27 May 2020) published a roadmap for a pharmaceutical strategy for Europe, soliciting that the "overall goal of this strategy, scheduled for adoption by the end of the year [2020], is to help ensure Europe's supply of safe and affordable medicines to meet patients' needs and support the European pharmaceutical industry to remain an innovator and world leader."[140] Although this appears promising, especially as regards the goal to supply affordable medicines (considering the two obligations of *availability* and *accessibility*) and support pharmaceutical companies in Europe, the issue is that there is no clear funding strategy for research on legal provisions that support the fight against epidemics/pandemics when they occur. In addition, there is no clear view on how control of pricing could be practiced. This calls for a thorough study on how large an R&D fund percentage is needed by public institutions to control the price, so that the governments (including the EU) meet the legal obligation of medicine *accessibility*. Therefore, there is a need for work towards the goal of having provisions that aid in funding pharmaceutical R&D (with precise proposals on the percentages needed to control prices), as well as clearly written patent exception clauses that are set to invoke at the start of a pandemic.

Seventh, regarding the use of some police powers (like in the cases of seizure of generic medicines in transit[141] in the Netherlands and Germany), this may lead to trade agreement problems, especially when there are bilateral treaties that define a patent as an investment and the pharmaceutical company (patent owner) as an investor. The recommendation here is for governments (especially when the EU signs agreements with non-EU states) to have clear clauses in their agreements (BITs) that show exactly where the pharmaceutical obligations and rights reside and to clarify when the right of "access to medicine" may be invoked by governments. The time is ripe for including the phrase "access to medicine" in treaties, as well as clear provisions on what would be expected from each party in case of a pandemic.

Eighth, this work recommends pharmaceutical companies to use the Medicines Patent Pool (MPP)[142] licenses to negotiate public health-driven licenses with patent owners and to sublicense to generic manufacturers in some cases. The MPP has well-written agreements with clear articles to protect both the pharmaceutical companies and the licensee.

Ninth, this paper recommends governments and pharmaceutical industries to focus on the following *four objectives* in delivering a vaccine: (i) satisfying the obligation of *quality*, (ii) on *time*, (iii) within *budget* (provisions to aid R&D funds), and (iv) with *supportive applicable* laws. Currently, we can witness pharmaceutical companies focusing on the first three objectives, and governments focusing on the first two. In other words, there is no support for R&D from governments. The reason is that there are no previously existing clear provisions on this to invoke during pandemics. More importantly, point (iv) is ignored entirely, even though we need laws to control the process of vaccine production and pricing. During the next pandemic, we cannot create applicable laws in real time. Hence, we need to be proactive now and create suitable provisions regarding "access to medicine." This would help us in future pandemics.

Tenth, the final recommendation is based on the fact that without a unified patent regime in the EU, it is not possible to achieve the four objectives mentioned above: delivering a quality vaccine, on time, within budget, and with supporting applicable laws. COVID-19 should be a wake-up call for governments in the EU to create a unified EU patent law, since it would surely speed up the processes that will help us strike a balance in this matter.

12. CONCLUSIONS

This paper highlights problems that require attention and makes some recommendations, because the current pandemic and those of the future require proactive legal measures so that uncontrollable suffering will not devastate the world further. Unfortunate delays that have led to suffering and death could be minimized by resolving the conflict between pharmaceutical patents and the human right of "access to medicine" in the current COVID-19 crisis and in future outbreaks. We cannot amend or create applicable and appropriate laws in "real time" during pandemics. We need to be proactive with suitable provisions on "access to medicine." In the conflict between patent laws and the human right of "access to medicine," the applicable norms identified in this paper are mainly the TRIPS/WTO regimes and the IHRL instruments of UDHR, ICCPR, ICESCR, CERD, ECHR, the EU Charter of Fundamental Rights, and the ESC. One helpful result of this work is the identification of legal problems that require attention, through an investigation of the intersection of laws and the need for CL or patent exceptions. Another result is a proposition of reorganization of the provisions that play into the conflict, with the goal of striking a suitable balance. The focus on the patent side is on Section 5 TRIPS (Articles 27–34), with Article 28 being the most relevant. On the human rights side, the proposed reorganization calls practitioners, policymakers, pharmaceutical industries, and institutions to focus on the overlap of critical medicine patents with Articles 4 and 15 ICESCR, Article 27 UDHR, Article 11 ESC (also reflecting Article 2 ECHR and Article 35 EU Charter of Fundamental Rights), Articles 4 and 6 ICCPR on protection of the right "to life." The legal obligations that IHRL has upon patent law (regarding access to medicine) are: *availability, accessibility, acceptability, and quality*. The paper divides case law into two groups: (i) no filing for expropriation, and (ii) filing for unlawful expropriation. The research adopts some previous work on balance (TRIPS flexibilities, ICESCR Article 15, the proportionality principle, exception clauses, and the police power doctrine) and adds some new ideas to their application. One of the ten recommendations in this work is amending WTO instruments on grounds of TRIPS Article 8(1), to allow WTO Member States to include IHRL as an applicable law to protect the human right of "access to medicine" and not be subject to attribution and responsibility. Another important recommendation is the use of MPP licenses for pharmaceutical companies. Lastly, to minimize the impact of the current pandemic and future disease outbreaks in the EU, this work recommends a unified EU patent law with specific provisions that can be invoked in the event of epidemics or pandemics, ensuring the right of "access to medicines."

[138] Hestermeyer (n 55) 255–287.

[139] Ben Upton, "National leaders to debate contentious budget increase for European research" (4 June 2020) Research Europe, Issue No 520.

[140] Ibid.

[141] WTO (n 86).

[142] Medicines Patent Pool (MPP) UNITAID (2020).

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Destruction of patent protected products manufactured outside Sweden

– Is Section 59 of the Swedish Patents Act on corrective measures contrary to EU law?

By Åsa Hellstadius, Håkan Borgenhäll

1. INTRODUCTION

The possibility for a patent holder that has suffered an infringement to apply for corrective measures such as, e.g. recall or destruction of the infringing goods serves the purpose of enforcing a court-ordered prohibition in practice and is an important tool in upholding the exclusive right. According to Section 59 of the Swedish Patents Act[1], *"upon a claim by a party that has suffered a patent infringement, the Court may, insofar as is reasonable, decide that a patent-protected product that has been manufactured without the consent of the patent holder shall be recalled from the channels of commerce, changed, taken into custody for the remainder of the patent term or be destroyed or that some other measure shall be taken in respect of it. The same applies to implements that have been, or have been intended to be, used in connection with the infringement."*[2]

The possibility for the courts to decide upon corrective measures such as, e.g. destruction, following a finding of patent infringement, has existed for a long time in Swedish patent law. Similar measures are found in the other Swedish intellectual property statutes. Since the implementation of the harmonisation measures pursuant to the Directive (2004/48/EC)[3] on the enforcement of intellectual property rights (the "Enforcement Directive"), the provisions governing corrective measures in Section 59 of the Swedish Patents Act must be interpreted in conformity with Article 10 of the Directive.

According to Article 10 of the Enforcement Directive, Member States shall ensure that the competent judicial authorities may order, at the request of the applicant, that appropriate measures be taken with regard to goods that they have found to be infringing an intellectual property right and, in appropriate cases, with regard to materials and implements principally used in the creation or manufacture of those goods. Such measures include, e.g. destruction. In considering a request for corrective measures, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account.
The principle of interpretation of national law in conformity with the provisions of an enacted directive is firmly anchored in EU law. But where the wording of a national provision is not in line with the corresponding directive provision, such directive-loyal interpretation may risk leading to legal uncertainty. Such issues arose in a case before the Swedish Patent and Market Court of Appeal (the "PMCA") in December 2020,[4] regarding the scope of Section 59 in the context of destruction of goods. In this case, an issue arose regarding the interpretation of Section 59 the Swedish Patents Act in conformity with Article 10 of the Enforcement Directive thereby trigging a question pertaining to the extent of such interpretation when the wording of the national provision is not in conformity with the wording of the Directive's provision.

2 THE PATENT AND MARKET COURT

2.1 The Reasons

The case concerned a patent infringement claimed by the plaintiff AstraZeneca AB versus the defendant Sandoz A/S. AstraZeneca alleged that Sandoz' marketing of the pharmaceutical *Fulvestrant Sandoz* amounted to an infringement of AstraZeneca's patent to the use of the pharmaceutical fulvestrant in the preparation of a pharmaceutical formulation for the treatment of a benign or malignant disease in the breast or reproductive tract by intra-muscular administration.[5] Sandoz had counterclaimed that the patent was invalid. In the event that the Patent and Market Court (the "PMC") would find that the patent was valid, Sandoz had admitted that the use of the pharmaceutical *Fulvestrant Sandoz* amounted to infringement of AstraZeneca's patent. However, Sandoz contested some of AstraZeneca's claims for relief, among them the claim based on Section 59 of the Patents Act for destruction of the *Fulvestrant Sandoz* products that Sandoz had or might have in their possession in Sweden.

The PMC found that the patent was valid and since Sandoz had admitted infringement in such situation, the Court, *inter alia*, proceeded to the interpretation of Section 59 of the Patents Act. Sandoz held that since the products in question were not manufactured in Sweden, Section 59 of the Patents Act was not applicable, and that it would neither be reasonable nor proportionate to order Sandoz to destroy the *Fulvestrant Sandoz* products. Sandoz argued that destruction as well as other corrective measures according to Section 59 of the Patents Act could only be applicable to a product which had been manufactured without the consent of the holder. This was apparent from the wording of the provision as Section 59 provides that the court may take such corrective measures against a patent protected product that has been manufactured without the consent of the patent holder (Sw. *"ett patentskyddat alster som har tillverkats utan patenthavarens lov"*). Sandoz held that since the manufacture of Fulvestrant Sandoz had not taken place in Sweden, but rather in a country without patent protection and then subsequently imported into Sweden, this manufacture had not required the consent of AstraZeneca. Thus, according to Sandoz, the products had not been manufactured in violation of the provisions of the Patents Act.

The question the PMC had to decide was how the scope of Section 59 should be interpreted. Following the wording of Section 59, the provision requires an unlawful manufacture, i.e. manufacture without the consent of the patent holder. In this case it was apparent that the manufacture was not contrary to the Swedish Patents Act since the absence of patent protection in the country of manufacture meant that it did not per se amount to an infringing act. The question was therefore whether the products manufactured in a country where no patent protection existed could still be considered to fall within the scope of Section 59 of the Patents Act and therefore be ordered for destruction.

Swedish legal commentators have indicated that Section 59 is probably not applicable in a situation as in the present case since the provision requires manufacture without the consent of the patent holder. If no unlawful manufacture has taken place, destruction by order of the court is not possible.[6] However, Article 10 of the Enforcement Directive concerns goods that have been found to be infringing an intellectual property right. It is the finding of infringement that qualifies the application of Article 10, regardless of the character of the infringing act. Thus, there is an apparent discrepancy between Section 59 of the Swedish Patents Act and Article 10 of the Enforcement Directive regarding the basis for the corrective measures according to these respective provisions.

This lacuna was not addressed by the Swedish legislator in the transposition process relating to the Enforcement Directive. On the contrary, it was held that the existing provisions in the Swedish intellectual property statutes regarding products which have been found to infringe an intellectual property right already corresponded to Article 10 of the Enforcement Directive and thus no amendments were proposed.[7] In the present situation, the PMC was thus required to find a suitable interpretation of Section 59 which balanced the an interpretation in conformity with Article 10 the Enforcement Directive without deviating too far from the wording of the Swedish provision, taking the principle of legal certainty into account.

1 59 § 1 st. patentlag (1968:839): "På yrkande av den som har lidit patentintrång får domstolen, efter vad som är skäligt, besluta att ett patentskyddat alster som har tillverkats utan patenthavarens lov ska återkallas från marknaden, ändras, sättas i förvar för återstoden av patenttiden eller förstöras eller att någon annan åtgärd ska vidtas med det. Detsamma gäller i fråga om hjälpmedel som har använts eller varit avsett att användas vid intrånget."

2 See the unofficial translation of the Swedish Patents Act by the Swedish Intellectual Property Office at: https://wwwtest.prv.se/globalassets/dokument/patent/informations-material/the-patents-act---unofficial-translation.pdf.

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

4 Case PMT 8135-19 of 18 December 2020, Sandoz A/S v. AstraZeneca AB.

5 EP 1 250 138 B2.

6 See, e.g. Holz, Nilsson, The Swedish Patents Act – A Commentary and Comparison with EPC and PCT (Sw. Patentlagen – en kommentar och en jämförelse med EPC och PCT), Jure 2012, p. 287.

7 See Government Bill 2008:09/67, p. 212.

2.2 The Findings

The PMC gave Section 59 a wide scope in line with the wording of Article 10 of the Enforcement Directive. The Court found that since Section 59 is based on the Enforcement Directive, the interpretation must be in line with the wording and purpose of the Directive. The PMC held that according to the relevant provision in the Directive, corrective measures may be taken against products that have been found to infringe a patent right. According to the PMC, the scope of the patent holder's exclusive right also includes import of products to Sweden which may have been manufactured in a country where no patent protection exists. Against this background, the PMC found that Sandoz' import of *Fulvestrant Sandoz* products to Sweden amounted to an infringement of AstraZeneca's exclusive rights. The imported products in question then became *"goods [...] found to be infringing"* in the meaning of Article 10 of the Enforcement Directive.

Thus, the PMC's interpretation clearly related more to the text of Article 10 of the Directive than to Section 59 of the Patents Act. In doing so, the PMC deviated quite far from the wording of the corresponding Swedish provision, which is clearly focused upon the act of manufacturing. The PMC also found that destruction of the products was reasonable under the circumstances, in order not to circumvent the patent protection. AstraZeneca's request for destruction of the Fulvestrant Sandoz products was thus granted.

3. THE PATENT AND MARKET COURT OF APPEAL

3.1 The Reasons

The case was appealed by Sandoz to the PMCA, where the patent was upheld. But the PMCA came to the opposite conclusion regarding the interpretation of Section 59 of the Patents Act, changed the decision of the PMC and revoked the decision to destroy the *Fulvestrant Sandoz* products. The PMCA found that there is a limit to the principle of interpretation in conformity with a directive and stated that too extensive interpretation or interpretation contrary to the wording of the national provision may conflict with the requirement of legal certainty.[8]

The PMCA held that the wording of Section 59 in the Swedish Patents Act clearly states that the goods that may be subject to corrective measures in the case of infringement are patent protected products which have been **manufactured without the consent of the patent holder** (our emphasis). The PMCA stated that the wording of Section 59 expresses that only such goods according to a certain infringing act, i.e. unlawful manufacturing, may be subject to corrective measures. Thus, the provision does not target infringing products in general, but it is specifically stated that it is unlawfully manufactured products that are covered by the provision.

The PMCA then proceeded to a comparison of the corresponding provisions on corrective measures in other Swedish intellectual property statutes and found that the wording of these statutes differs regarding what type of products that may be subject to corrective measures. Some of the statutes focus on the products that are subject to the infringement in question, whereas other statutes (including the Patents Act) state that it is such products that may be tied to a particular act of infringement (e.g. manufacture) that are covered by the provisions of corrective measures. The PMCA held that this difference in wording could not be disregarded in the assessment of whether the conditions for destruction were fulfilled in the present case, regardless of whether the intention of the legislator in the implementation of the Enforcement Directive seems to have been that all goods found to be infringing should be covered by the provisions in question.[9]

[8] See p. 18 of the judgment: "Alltför vidsträckta tolkningar eller tolkningar i strid med den nationella bestämmelsens ordalydelse kan dock strida mot kravet på rättssäkerhet." The PMCA further referred to cases and doctrinal works, e.g. the Court of Justice of the European Union, Judgment of 4 July 2006, Adeneler and Others, C-212/04, ECLI:EU:C:2006:443, paragraphs 108-111.

[9] See Government Bill 2008/09:67, p. 212.

[10] See Government Bill 2008:09/67, p. 212.

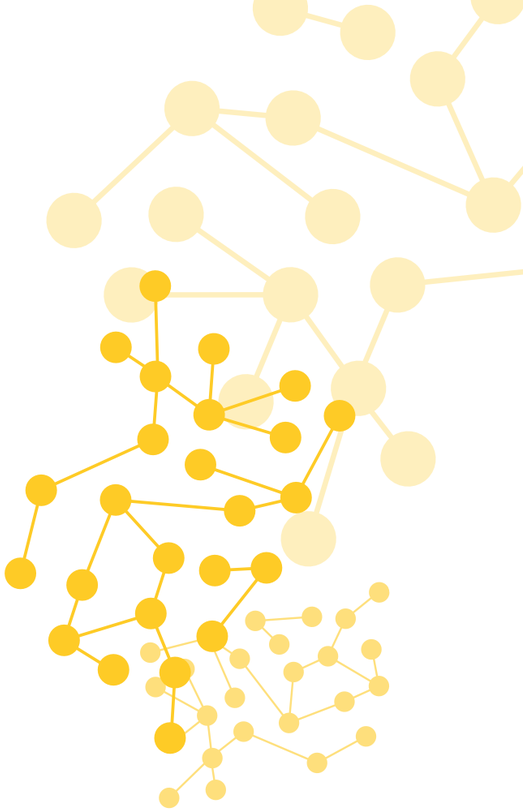
[11] The proposal for a new Swedish Patents Act does not address this issue (Swedish Government Official Report 2015:41 Ny Patentlag).

3.2 The Findings

The PMCA went on to state that AstraZeneca's request for destruction was essentially based on Sandoz' infringement of AstraZeneca's patent rights. AstraZeneca had neither claimed, nor invoked any evidence in support of, its assertion that the products in question were unlawfully manufactured. The PMCA held that the scope of application of Section 59 of the Patents Act cannot be extended to also include such goods that are not explicitly covered by the provision in question. The PMCA noted that such an extensive interpretation is neither appropriate nor possible. Thus, since the manufacturing of Sandoz' products was not per se an infringement of AstraZeneca's patent rights, Section 59 could not be applied to grant AstraZeneca's request for destruction of the products in the present situation. The PMCA granted Sandoz' appeal in this part and revoked the PMC's decision pertaining to destruction of the products.

4. COMMENTS

The PMCA's decision draws attention to a conflict between the Swedish provisions on corrective measures and the corresponding provision in Article 10 of the Enforcement Directive. The legislator did not seem to be aware of this problem at the time of implementation of the Enforcement Directive.[10] It has not been discussed in later legislative works either.[11] The decision draws an interesting line between the duty to conform by interpretative means to secondary EU legislation and adherence to the wording of national provisions in a harmonised field of law, in the interest of legal certainty. It seems as if the PMCA has identified a limit to the possibilities of extensive interpretation of national law with the purpose of conforming to EU law. Thus, it presently falls upon the Swedish legislator to attend to the discrepancy between Swedish law and EU law regarding the scope of application for corrective measures in intellectual property law.



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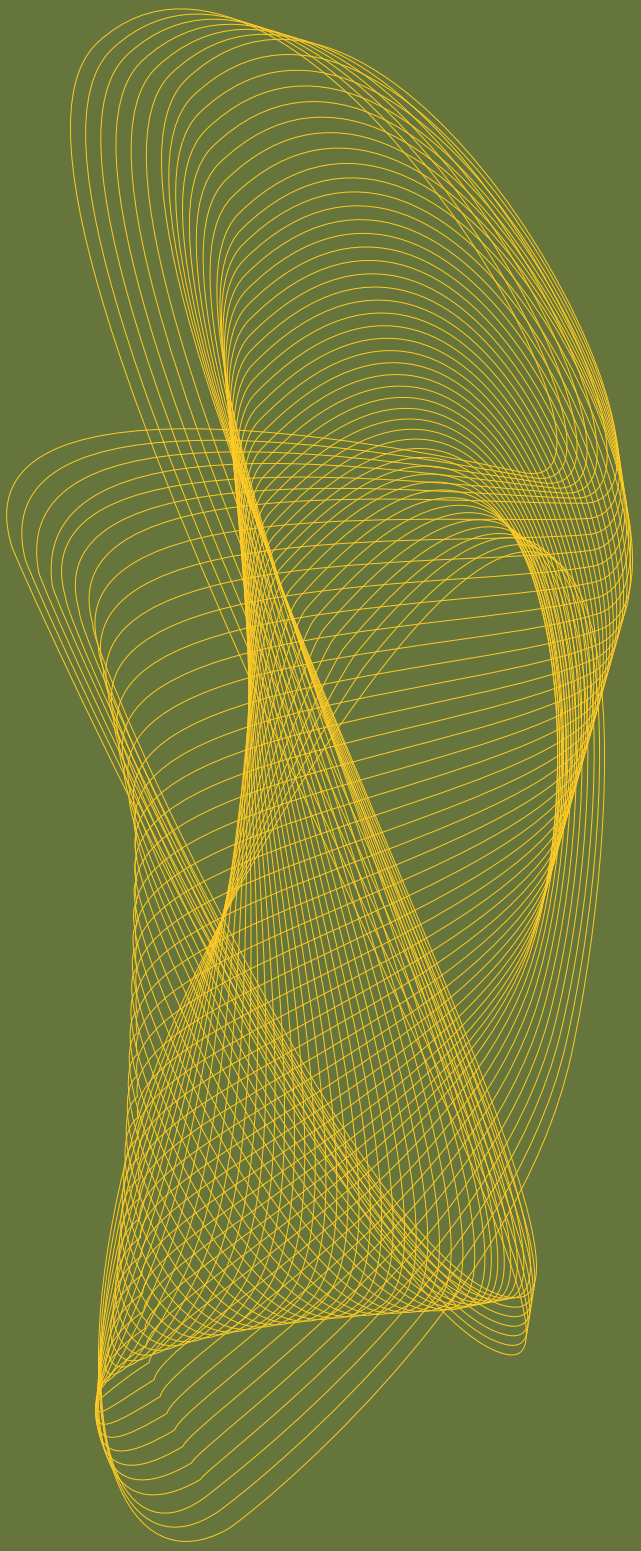
Åsa has extensive academic research and teaching experience in intellectual property law and market law (doctor of laws, associate professor), with a special focus on patent law, biotech and pharmaceutical matters. Her practices are in all types of intellectual property and market law disputes, and she advises on a broad range of issues.



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