Pepper decision - plants and animals get chilli reception at EPO

Dr Ben Tolley and Dr Nick Sutcliffe of the Life Sciences team at Mewburn Ellis LLP look at the extensive ramifications of this landmark case.
Welcome to the third issue of The Life Sciences Lawyer magazine, and my first as Editor here at CTC Legal Media. I am excited to make your acquaintance and look forward to bringing you the latest law developments in life sciences from hereon in. I have been working with The Life Sciences Lawyer since its launch earlier this year, so, with my background being in English (BA Hons), you can imagine my delight in becoming Editor. It will be great to hear from you, do get in touch.

I thank Matt Seex, my predecessor, for his insight and wish him well with his new beginning.

For this issue, our cover story, brought to us by Mewburn Ellis, explains the reason the G3/19 has suffered backlash from plant breeders associations, and how EPA both ‘had its cake and ate it’ in respect to the changes in patenting in the sector. Further, Janett Lumbreras discusses the uses for cannabis for medical and industrial use, and the modified production of cannabis to maximise yield and reduce THC properties. We also touch on life sciences disputes from the specialists at WIPO with a close glance at their experiences.

This and an in-depth analysis, from Baker McKenzie, of the changes enforced in pharmaceutical patent rights with the replacement of NAFTA with USMCA, plus more in the developments of life sciences law.

I hope you enjoy the issue.

Faye Waters
Editor

Mission statement
The Life Sciences Lawyer educates and informs professionals working in the industry by disseminating and expanding knowledge globally. It features articles written by people at the top of their fields of expertise, which contain not just the facts but analysis and opinion. Important judgments are examined in case studies and topical issues are reviewed in longer feature articles.
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Pepper decision means conventionally bred plants and animals get a chilli reception at the EPO

Dr Ben Tolley and Dr Nick Sutcliffe of the Life Sciences team at Mewburn Ellis LLP look at the extensive ramifications of this landmark case.

Following decision G3/19 (“Pepper”) of the Enlarged Board of Appeal (EBA), plants and animals obtained from “essentially biological” processes will no longer be patentable before the European Patent Office (EPO). This decision has far-reaching implications pending European patent applications filed after 1 July 2017, when Rule 28(2) EPC was introduced.

For some time at the EPO, plant varieties and “essentially biological” processes for the production of plants and animals have been excluded from patent protection under Article 53 EPC (confirmed in “Broccoli” G2/13) and “Tomato” G2/12 decisions, which concluded that the exclusion of “essentially biological” processes did not extend to products of those methods.

Despite providing much needed clarity and certainty, these decisions were not received favorably by some groups, especially plant breeders associations who argued that allowing the patenting of plants resulting from classical breeding is an unfair intrusion into the territory of plant variety rights (PVRs).

Whilst the EBA’s decision in G3/19 significantly changes the situation regarding the patent eligibility of plants, the decision itself concerns Rule 28(2) EPC, which was introduced by the Administrative Council (ACA) on 1 July 2017. Its introduction followed lobbying and pressure from the European Union to limit the extent of patent protection available in this field in the form of a resolution by the European Parliament in December 2015 and a non-binding notice from the European Commission in November 2016. The change to the rules was extremely controversial, particularly in the absence of a reference to the European Court of Justice on the matter.

The effect of the change was also unclear, with the Board of Appeal in T1063/17 ruling that Rule 28(2) EPC was, as many had anticipated, in conflict with Article 53(b) EPC (as interpreted by G2/12 and G2/13) and should therefore be ignored and declaring their intention to reach a similar conclusion in T2734/18. Following the issuance of T1063/18, the European Parliament issued a second resolution in September 2019 re-stating their view that the products of conventional biotechnological techniques and classical breeding techniques providing that the resulting product was new, inventive and could be reproduced reliably. This had been confirmed on several occasions including by the EBA: the highest decision-making authority at the EPO in the combined “Broccoli II” (G2/13) and “Tomato II” (G2/12) decisions, which concluded that the exclusion of “essentially biological” processes did not extend to products of those methods.

Q3/19 – what has changed?

Until G3/19, it was possible to obtain patent claims to plants and animals or material thereof (e.g. fruit or seeds) resulting from breeding processes “must not become patentable”. The vigor with which EU institutions have pursued this issue reflects the strength of the concerns of the plant breeding industry and various pressure groups about the monopolization of plant genetic resources.

In deliberating on this issue in G3/19, the EBA therefore faced considerable pressure from both inside and outside the EPO to find a way to maintain the validity of new Rule 28(2) EPC despite the existence of its own earlier case law. In the face of this pressure, the EBA found a way to maintain the validity of both new Rule 28(2) EPC and G2/12 and G2/13. In other words, the EBA both had its cake and ate it. The key to reaching this solution was the adoption of so-called “dynamic interpretation” of Article 53(b) EPC. This allowed the EBA to conclude that the correct interpretation of Article 53(b) EPC was set out in G2/12 and G2/13 but was altered by the subsequent implementation of Rule 28(2) EPC. According to the EBA, the new interpretation that is set out in new Rule 28(2) EPC applies to applications filed after the rule was implemented on 1 July 2017. Applications filed before that date will not be affected by Rule 28(2) EPC and will continue to be examined according to the previous interpretation of Article 53(b) EPC set out in G2/12 and G2/13. Since the decision cannot be appealed, G3/19 therefore gives a clear-cut date for the prohibition on plants and animals produced by “essentially biological” processes, which does

Résumés

Dr Ben Tolley, Associate, European Patent Attorney

Ben does patent work in the life sciences sector with a particular focus on plant sciences. This includes drafting and prosecuting UK, European and International patent applications. The majority of his practice is engaged in ‘defending’ or ‘attacking’ patents in opposition and appeal proceedings before the EPO.

Dr Nick Sutcliffe, Partner, European Patent Attorney

Nick works across the full range of patent activity in the life sciences sector, from pre-filing advice and drafting of applications to worldwide portfolio management, prosecution and appeal. He is also experienced in defensive and offensive European oppositions and due diligence work.

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at least provide some immediate clarity for patent applicants in the Agritech sector.

Although in some respects G3/19 provides a pragmatic solution to a thorny legal issue, the way the decision was reached and the fundamental contradiction in the interpretation of Article 53 involves some negative consequences for legal certainty at the EPO more generally. Whilst the EBA has always had the power to amend its case law by the PVR system to protect their products. Depending on the species, the PVR system to protect their products. Depending on the species, the PVR system to protect their products. Depending on the species, the PVR system to protect their products. Depending on the species, the PVR system to protect their products.
There are a number of different ways of solving a dispute in the life sciences sector. Examining these in detail are Chiara Accornero, Legal Officer and Representative of the WIPO Arbitration and Mediation Center in Singapore, Heike Wollgast, Head, IP Disputes Section, WIPO Arbitration and Mediation Center, and Sally Shorthose, partner in the Bird & Bird Life Sciences and Intellectual Property Group.

In this article we consider the particular challenges and opportunities which arise in the course of life sciences disputes, and the advantages and disadvantages of various types of dispute resolution. Given the investment in time and money that stakeholders put into their products and collaborations, a simple win/ lose situation is not necessarily a possible or desirable outcome. With skill and application, relationships can be mended, and reputations can remain intact without the cost, time, and publicity of a high profile, possibly multijurisdictional, court case.

Life Sciences Disputes

Life sciences disputes have distinctive characteristics that should be considered when choosing the appropriate dispute resolution strategy. For example, intellectual property (IP) is often the crux of development and exploitation and players will want to do their best to protect the value of that IP (whether patents, trademarks, know how or trade secrets). However, with regulatory and patent limitations, lifecycle of life sciences can be relatively short and therefore, avoiding costly and lengthy litigation is of prime interest for all parties involved.

Life sciences collaborations often involve multiple parties, some, or all of whom may be located in different geographic areas thereby bringing in the laws of multiple jurisdictions, as well as different business and legal cultures. This is particularly true as cross-border licensing becomes increasingly commonplace, or in the case of research and development projects, which can have a truly cross-border dimension. The choice of the appropriate forum is therefore of key consideration, to avoid conflicting results in simultaneous court proceedings in different countries, to ensure the neutrality of the court, avoiding unfamiliar procedural practices and a lack of enforceability of court judgments outside the jurisdiction where they were obtained.

The subject matter involved in life sciences disputes is often specific.

Mediation and Arbitration

Mediation encompasses a range of private dispute resolution mechanisms that allow parties to resolve their dispute in a more flexible, time and cost efficient way, giving parties control over the process and the possibility to select one or several independent mediators and arbitrators.

Mediation is an informal procedure in which the parties request the mediator to assist them to settle their dispute. The mediator facilitates the settlement process by furthering dialogue between the parties and helping them to identify their underlying interests and to reach mutually satisfactory solutions.

Arbitration is a formal procedure, whereby parties submit their dispute to one or several arbitrators who render a final and binding decision, the arbitral award, which is normally final and not subject to appeal. Expedited Arbitration is an arbitration procedure that is carried out in a short time and at a reduced cost.

Mediation and arbitration differ in terms of procedural formality, party control and finality, and each option offers uniquely appropriate to particular circumstances. Mediation and arbitration can also be combined to accommodate the advantages of the different procedures, by having for instance a first mediation phase, followed, in the event of a failure to reach settlement within a designated period of time, by expedited arbitration.

Advantages of Mediation and Arbitration for Life Sciences Disputes

The potential of mediation and arbitration in the field of life sciences is significant. Mediation and arbitration have features that, if well managed, can translate into substantial time and cost savings and commercially useful outcomes, making them a more affordable and flexible avenue for life sciences disputes.

Their main advantages include:

- **Party Autonomy:** because of their private nature, mediation and arbitration offer parties the opportunity to exercise greater control over the way their dispute is resolved. Depending on their needs, they can select streamlined or more extensive procedures, choose the mediator or arbitrator, rules and procedures, place, and language of the proceedings. The WIPO Mediation, Arbitration and Expert Determination Rules (WIPO Rules) are entirely open to being modified by party agreement, while at the same time providing a firm procedural basis where the parties have not determined otherwise.

- **Single procedure:** mediation and arbitration allow multiple issues and rights arising under several jurisdictions to be addressed in a single process, thereby avoiding the expense and complexity of separate concurrent litigation, as well as the risk of inconsistent results. The

### The subject matter involved in life sciences disputes is often specific.

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**Résumés**

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Chiara holds a Master of Laws from the University of Turin and a Certificate in Transnational Law from the University of Geneva. Chiara joined the WIPO Arbitration and Mediation Center in Geneva in 2016 and is currently the representative of the WIPO Center at Maxwell Chambers in Singapore.

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Heike holds a Ph.D. in European Community Law from the University of Cologne, Germany. Prior to joining the WIPO Center in 2012, she worked for two major law firms in Germany in the areas of trade and intellectual property law and specialized in legal and policy aspects of intellectual property enforcement at WIPO’s Building Request for IP Division.

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Sally joined Bird & Bird in September 2006 as a partner in the Life Sciences and Intellectual Property Group, based in London. Sally spent 11 years working in-house firstly at ICI/Zeneca and latterly as Legal Director of Novartis UK. She specialises in transactional IP work and life sciences regulatory work. She is also the head of the Kluwer Law publishing, the EU Guide to Pharmaceutical Regulatory Law.

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**Arbitration**

**WIPO arbitration and mediation for life sciences disputes**

1 https://www.wipo.int/amc/en/mediation/
2 https://www.wipo.int/amc/en/arbitration/
3 https://www.wipo.int/amc/en/mediation/what-is-exp-arb.html
6 https://www.wipo.int/amc/en/rules/

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**International**

International enforcement provided by the New York Convention[4] and more recently the Singapore Convention[5] ensures that arbitral awards and settlement agreements resulting from mediation are complied with internationally. The WIPO Mediation Rules have been updated in 2020 to facilitate the enforcement of settlement agreements as may be required under the Singapore Convention[6].

**Time and cost:** mediation and arbitration allow parties to save significant costs that the parties would otherwise incur in multi-jurisdictional court proceedings. The WIPO Center places emphasis on containing the time and cost of proceedings conducted under WIPO Rules. A typical WIPO Mediation takes four months but may be completed more rapidly on the request of the parties, for instance to ensure compliance with timelines in court referrals. Parties may also opt for the procedural framework established by the WIPO Expedited Arbitration Rules.

**WIPO expedited arbitration proceedings**
have been concluded with a final award in as little as five weeks.

**Expertise:** in mediation and arbitration, parties can select their mediator or arbitrator. The WIPO Center maintains a list of mediators and arbitrators specializing in all areas of IP (including life sciences) that parties can appoint in WIPO cases. The WIPO Rules contain specific provisions governing the confidentiality of the existence of the mediation and arbitration, disclosures made during the process and any outcome.

**Confidentiality:** except where otherwise required by law, mediation and arbitration allow parties to keep the proceedings and the outcome confidential. Confidential dispute resolution helps parties to focus on the merits of their dispute without fear of adverse publicity and to preserve the parties’ business relationships and reputations. The WIPO Rules set extensive provisions governing the confidentiality of the existence of the mediation and arbitration, disclosures made during the process and any outcome.

**Preserving business relationships:** mediation gives the parties the opportunity to go beyond the legalistic resolution of the dispute to negotiate creative solutions that satisfy their business interests, including preserving existing business relationships, or forging new ones. More than 70% of WIPO mediation procedures settle and even in arbitration, 33% of WIPO cases are settled by the parties before any formal decision was issued.

**How to Submit a Dispute to WIPO Mediation and Arbitration**

Mediation and arbitration are consensual procedures, in that they can only be used if all parties consent to submit their dispute to it. For future disputes, such consent can be achieved through the inclusion of a mediation or arbitration clause in a contract, and for existing disputes through the conclusion of a mediation or arbitration submission agreement. To facilitate such party agreement, the WIPO Center provides recommended contract clauses and submission agreements.

**Mediation** allows the parties to continue to cooperate towards the development of a creative solution that satisfies their interests in the best possible manner. Mediation is available at the WIPO Center, the mediator issued a protective order pursuant to the WIPO Mediation Rules to prevent the claimant from accessing certain confidential documents disclosing the respondent’s business secrets.

**Arbitration** allows the parties to dispute the settlement of the issues in dispute between the parties in any manner that the mediator believes to be appropriate. Also in arbitration, Article 67 provides that arbitrators can suggest that parties explore settlement at such times as they may deem appropriate. If the parties agree on a settlement of the dispute before the award is made, arbitrators may terminate the arbitration and record the settlement in the form of a consent award, if requested by the parties.

**WIPO Mediation Rules** are the WIPO Mediation Rules. The WIPO Mediation Rules are available at the WIPO Center’s website, which provides online case administration options, including an online docket. WIPO eADR is protected and encrypted to ensure confidentiality. Further information on WIPO eADR is available at: www.wipo.int/amc/en/wipo_eadr/wipo_eadr.html.

**When parties and neutrals in WIPO cases are based in different locations, they have occasionally agreed to hold meetings or hearings remotely via online tools, including videoconferencing facilities, or telephone.**

**A WIPO Arbitration of a Pharma Dispute**

A European biotech company, holder of several process patents for the extraction and purification of a compound with medical uses, entered into a license and development agreement with a large pharmaceutical company. The parties included in their contract a clause stating that all disputes arising out of their agreement would be resolved by a sole arbitrator under the WIPO Arbitration Rules.

Following the signing of the agreement, the biotech company terminated the contract, alleging that the pharmaceutical company had deliberately delayed the development of the biotech compound. The biotech company commenced WIPO Arbitration claiming substantial damages.

The WIPO Center proposed a number of candidates with considerable expertise in biotech/pharma disputes, one of whom was chosen by the parties. Having received the parties’ written submissions, the arbitrator held a three-day hearing in Geneva (Switzerland) for the examination of witnesses. This not only served for the presentation of evidence but also allowed the parties to re-establish a dialogue. In the course of the hearing, the arbitrator began to think that it would be in the interest of the parties to continue to cooperate towards the development of the biotech compound.

On the last day of the hearing, the parties accepted the arbitrator’s suggestion that they should hold a private meeting (please add reference to Article 63 of the Rules). As a result of that meeting, the parties agreed to settle their dispute and continued to cooperate towards the development and commercialization of the biotech compound.

**Conclusion**

As has been described above, there are a number of different ways of solving a dispute in the life sciences sector. The advantages of alternative forms of dispute resolution are that they can provide flexibility, expertise, and a confidential forum within which transparency is encouraged and an opportunity to explore innovative solutions is provided, which solutions often result in a continuation of business relationships.
The future of medicine: ATMPs

Fieldfisher’s Cliodhna McDonough, Legal Director, James Gallagher, Associate, and Emily Lockey, trainee solicitor, look at this critically important and rapidly developing area.

Patent medical treatments are seeing a paradigm shift towards one of cure from that of a traditional disease management approach. Advanced therapy medicinal products (ATMPs) are a group of medicines for human use that are based on genes, tissues or cells which hold promise as treatments for a variety of previously untreatable and high-burden diseases. There are three main types of ATMP:

1. Somatic cell therapies consist of a mixture of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions, or structural properties relevant for the intended clinical use have been altered.
2. Gene therapy medicinal products contain an active substance consisting of a recombinant nucleic acid used in or administered to humans to regulate, repair, replace, add or delete a genetic sequence, with the therapeutic, prophylactic, or diagnostic effect relating directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence.
3. Tissue engineered products consist or consists of engineered cells or tissues and is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing, or replacing a human tissue.

In addition, some ATMPs referred to as “combinant ATMPs” also contain one or more medical devices as an integral part of the medicine (e.g. cells embedded in a biodegradable matrix or scaffold).

In the EU, ATMPs are primarily governed by Regulation 1394/2007 (the ATMP Regulation) which provides for classification and evaluation of these products by a specialized committee within the European Medicines Agency (EMA), the Committee for Advanced Therapies (“CAT”). who prepare a draft opinion before the Committee for Medicinal Products for Human Use (“CHMP”), adopts a final opinion and a market authorization (MA) is granted by the EU Commission. The ATMP Regulation also empowers Member States to permit the use of advanced therapies that are not authorized by the EU Commission, subject to certain conditions being satisfied, the so-called “hospital exemption”.

Obstacles to market

However, there are tremendous challenges to the commercialization of these products, which require new and innovative approaches to ensure patients receive the efficacy of the products that is comparable to that of traditional pharmaceutical products. The success of ATMPs is dependent on the use of science and risk-based approaches to their development and manufacture. Over the next few years, the regulatory requirements and industry practices will continue to be significantly developed and become benchmarks.

As a development stage, recent research carried out by the Alliance for Regenerative Medicine (ARM) has highlighted that whereas the number of new ATMP clinical trials has increased significantly over a 4-year period on a global scale (+32% from Jan 2014 to June 2018), with notable growth in North America and Asia, this trend is not reflected in Europe. Within Europe, significant country-by-country variability in the number of clinical trials, speed of assessment, and time for approval of clinical trials has also been observed, with the UK, Spain, and France attracting the highest number of ATMP clinical trials during the same 4-year period (132, 102, and 101, respectively). Survey respondents also indicated that the most important criteria for selecting a clinical trial site and a host country are the availability of local clinical expertise and suitable healthcare facilities; followed by the speed of approval, the quality of review, and the expertise of local regulatory authorities. The authors also speculated that fragmentation of regulatory/ethical guidance and a lack of harmonization on various other factors (e.g. donor testing requirements, patient consent forms, contracting agreements, etc.) across European countries may also make for a less attractive environment for clinical trials. As a further example, a possible cause of the relatively low number of gene therapy clinical trials being compared to North America was also traced back to the classification of some of these therapies as GMOs, requiring specific approval by different national authorities, a step that adds complexity to the clinical trial authorization process and often extends the time required for approval.

From a commercial point of view, ATMPs present a different scenario to that of pharmaceutical medicines in that there is not a classic supply and demand model, largely because ATMP therapies are more likely to have a patent put to full use in a medical need. In addition, the clinical development of ATMPs does not typically follow conventional clinical trial phases, unlike traditional medicine. It is often the case with rare disease indications, that ATMP clinical programs are compressed into one or two clinical studies, followed by conditional approval with post-marketing requirements. To this end, ATMPs often utilize Early Access Programs, which allow for supply to patients prior to marketing approval. Compliance with good manufacturing practices (GMP) is mandatory for ATMP products. New GMP guidelines on ATMPs from the European Commission (EC) came into force in 2018. These guidelines apply to ATMPs with market authorization, investigational ATMPs and those administered to patients under Article 3(7) of Directive 2001/83/EC (the “hospital exemption”). The guidelines seek to reflect the rapid technological and medical advancements being made in the field and recognize the need for a certain degree of flexibility so that manufacturers can implement measures most appropriate to the specific characteristics of their product. As such, the guidelines allow for a risk-based approach, giving manufacturers more autonomy over the production process. The Pharmaceutical Inspection Co-operation Scheme Committee (PIC/S) has expressed concerns about the impact of the new GMPs on public health and the safety of patients, suggesting that the new guidelines lower the GMP standards. The PIC/S produce their own GMP guidelines, which, until now, have not been developed in parallel with EC guidelines. The development of stand-alone EC guidelines on ATMPs has therefore led to an unwieldy, non-harmonized approach to GMP regulation.

The PIC/S are currently developing revisions to their own guidelines to account for the international developments in the regulation of ATMPs, with particular attention given to the EC guidelines, whilst also addressing any concerns related to patient safety and the proportionate regulation of ATMPs.

The challenge for manufacturers will now be to check whether their current established processes are in accordance with the new guidelines, including any revisions made to the PIC/S guidelines, or whether any changes or additional activities will be necessary.

ATMPs are a group of medicines for human use that are based on genes, tissues or cells.

The ATMP field is rapidly moving from pure science focus, led by small industry and universities, to a focus on how to commercialize such therapies. The high cost of ATMPs is predominantly driven by the small scale of manufacturing, the high degree of scientific testing required for the products and the need for substantial manipulation so that biological characteristics, physiological functions, or structural properties relevant for the intended clinical use have been altered.

Résumés

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for ongoing patient monitoring testing which combined requires significant capital investment. Reimbursement of ATMPs is frequently mentioned as a major hurdle, both from a developer and health technology assessment (HTA) body point of view, as the manufacturing of ATMPs is considered more expensive by nature and is expected to pose pressure on healthcare budget. Combining these two ATMP pipelines with the prospect of healthcare budget constraints, sustainable ATMP reimbursement has become the next major challenge in this field.

Talking logistics: Supply chain challenges
One of the main barriers to commercial viability for ATMPs is the supply chain, which contributes significantly to the overall cost of goods and is limited by infrastructure, temperature requirements and, of course, the time frame for transportation taking into consideration cell viability. Poor co-ordination of supply and logistic conditions have the potential to negatively affect the quality of ATMPs.

Unlike traditional medicines, living cells have a short shelf life of between 1 to 3 days at ambient temperature conditions. Therefore, ATMPs require a quick delivery time from finished product to administration to a patient. Manufacturing and the short shelf life of the product require tight controls on logistical arrangements, which adhere to Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and the EU Falsified Medicine Directive, in addition to the trace-and-track regulations prescribed throughout the supply chain as is compliance with the trace-and-track regulations prescribed by GDP and the EU Falsified Medicine Directive to monitor and control the safety and supply of medicines for human use. For example, the CII is a national database that tracks medicines from manufacture to administration to a patient.

As part of the journey to the patient, the product should be delivered from the manufacturer into the relevant country’s facility where it will be stored until Qualified Person (QP) release. The QP should be familiar with sample collection, supply chain, and manufacturing processes. Critical sites should also provide appropriate facilities and licenses for the storage and preparation of ATMPs. The absence of GMP for example deep freezers, liquid nitrogen storage, cryopreservation, and GMO laboratories may restrict the use of clinical sites.

Traceability and control remains a constant requirement throughout the supply chain. The challenge is that a therapy must not be administered to the wrong person; if that happens, the results could be catastrophic. Thus, a chain of custody is paramount, as the therapy changes hands among supply chain participants. The stakeholders of an ATMP supply chain are interdependent and must communicate and share data to provide transparency along the channel, while also assuring that sensitive patient data is appropriately protected. Manufacturers should outline a robust front-end supply chain and logistics planning strategy along with a thorough risk management assessment to help identify which factors in the chain might in turn influence manufacturing decisions.

As the shelf life of ‘one-size fits all’ towards personalized therapeutic strategies for biological processes continues apace, the regulatory landscape associated with the development and commercialization of these treatments will continue to evolve. The challenges faced by manufacturers in adopting their processes and systems to ensure compliance with these requirements will also continue to change as new treatments and technologies are considered for scale-up and commercialization. For the organizations that can navigate this shifting landscape however, the rewards associated with successfully delivering life-changing and often life-saving treatments to patients are within reach.

Combined ATMPs may also contain medical devices as an integral part of the medicine.

Osamu Yamamoto, patent attorney and partner at Yuasa and Hara, gives an IP overview of this important technology.

### Résumé

Mr. Yamamoto is a patent attorney; and a partner of YUASA and HAR A. He has extensive experience in pharmaceutical and biotechnology research and development at a chemical company for ten years before specializing in intellectual property. He has represented a variety of companies in the fields of pharmaceuticals, biotechnology, diagnostics, and food and beverages.

He is experienced in all aspect of patent issues, including drafting patent applications, dealing with Office Actions, providing expert opinions, defending or attacking patent rights in invalidation trials and oppositions, and patent infringement litigations.

### Inventor of CRISPR-Cas9

Jennifer Douste and Prof. Emmanuelne Charpentier focused on the protein designated Cas9 (CRISPR associated protein 9), and discovered that:

1. foreign DNA is incorporated into CRISPR domain by Cas9.
2. Cas9 forms a complex with guide-strand RNA.
3. Cas9 cleaves double-stranded DNA complementary to guide-strand RNA.

Based on their discovery, the University of California and the University of Vienna (UC et al) filed a US provisional application on 25 May 2012. Earlier than UC et al, Vriëns University in Lithuania filed a US provisional application relating to the technology on 20 March 2012. Neither of the US provisional applications included any data showing application of CRISPR-Cas9 in eukaryotic cells.

Shortly after the filings by the two groups, three other groups filed US provisional applications showing practical application of CRISPR-Cas9 to eukaryotic cells. The three groups to file were: TaloGen Incorporated, on 23 October 2012; Sigma Aldrich Corporation, on 6 December 2012; and Broad Institute Inc and MIT (Broad et al), on 12 December 2012. Each of the three groups filed PCT applications claiming priority from the first filed application (and some others).

### Patents in Japan

Please refer to the table above right showing the status in Japan of the PCT applications.

PCT/JP2012/038782, filed by UC et al entered the national phase in Japan and was allowed on 8 May 2018 (JP 6343506). It covers broader concepts than the applications by the other groups. Additionally, a divisional application was recently granted for patent JP 609886, and one further divisional application remains pending.
PCT

Japan

Granted

PCT/US2013/073306
PCT/US2013/032580
PCT/US2013/032581
PCT/US2013/073307
PCT/US2013/073346
PCT/US2013/073347
PCT/US2013/074819
PCT/US2013/074743

Pending

Application 2018-018574
Application 2019-000951
Application 2018-18948
Application 2018-097613
Application 2019-003997
Application 2019-090391

Rejected

Application 2016-175672
(Application 2017-017590)
Application 2015-547573
(Application No. 2016-137720
(Application 2017-017796
Case 1: Hei 31 Gyo-ke 10010)

As for Broad et al., a divisional application derived from the national phase application entered in Japan from PCT/US2013/074819 was allowed on 31 July 2017 (JP 6203879) and was the first granted patent on CRISPR-Cas9 was allowed on 31 July 2017 (JP 6203879) and entered in Japan from PCT/US2013/074819, as of the end of June 2020, the five groups. From PCT/US2013/074819, as of the end of June 2020, one divisional application and two second generation divisional applications have been granted. JP 6203879, and JP 6493005, respectively, two divisional applications are pending at the examination stage. Further, one divisional application (Application 2016-175740) was rejected by the JPO appeal board (Appeal 2017-017590), and the case was brought to the Intellectual Property High Court (IPHC), and the IPHC rejected the demand (Case 1 below).

Broad et al. also filed the national phase applications from PCT/US2013/074743 as shown in the table.

The reasons for rejection were prior art effect rejection.

Case 1

As stated above, one divisional application was rejected by the JPO appeal board (Appeal 2017-137795). The reasons for rejection were prior art effect rejection under Article 29(2) of the Patent Act and lack of inventive step on 25 February 2020, are explained below.

Claim 1

An engineered, non-naturally occurring CRISPR-Cas vector system, comprising one or more vector systems comprising:

(a) a first regulatory element operably

linked to a nucleotide sequence encoding a CRISPR-Cas system polynucleotide sequence comprising a guide sequence, a tracrRNA and a tracr mate sequence, wherein said guide sequence hybridizes to one or more target sequences in a polynucleotide locus in a eukaryotic cell;

(b) a second regulatory element operably

linked to a nucleotide sequence encoding a type II Cas9 protein, and

(c) recombination template, wherein components (a), (b), and (c) are located on the same or different vectors of the system, and the system further comprises one or more nuclear localization signals(s) expressed with the nucleotide sequences encoding Cas9 protein, and thereby the guiding sequence targets the one or more polynucleotide loci in a eukaryotic cell, and Cas9 protein cleaves the one or more polynucleotide loci, whereby the sequence of the one or more polynucleotide loci is altered.

The JPO focused on the issue of prior art effect rejection under Article 29(2) of the Patent Act. Broad et al. asserted that Citation 1 (Science; Aug 2012; Vol. 337; pp. 816-821: by the Broad et al) with respect to the same or different vectors of the system, and the system further comprises one or more nuclear localization signals(s) expressed with the nucleotide sequences encoding Cas9 protein, and thereby the guiding sequence targets the one or more polynucleotide loci in a eukaryotic cell, and Cas9 protein cleaves the one or more polynucleotide loci, whereby the sequence of the one or more polynucleotide loci is altered.

The IPHC dismissed Broad et al. assertion stating that the facts “guide RNA leads Cas9 protein to a target part in genome sequences in eukaryotic cells, and Cas9 leads cleavages of double strand genome DNA at the target part, and the cleavage of the double strand is repaired in the process of DNA repair in a manner the genome sequences are modified” is substantially disclosed in Citation 1. The IPHC did not judge the issue of inventive step in view of Citation 2 (Science; Aug 2012; Vol. 337, pp. 816-821: by group of Prof. Doudna).

Case 2

The national phase application entered in Japan from the Broad et al application PCT/US2013/074743 was allowed on 20 May 2019 (JP 6549621) and an opposition was subsequently filed against the patent on 17 January 2020 (Opposition 2020-700032). The patented claims set forth “tracr sequence has a length of 40 or more nucleotides”. The subject of Case 2 is a divisional application (Application 2016-128599) derived from the national phase application of PCT/US2013/074743.

The JPO appeal board rejected the application on ground of prior art effect under Article 29(2) of the Patent Act and lack of inventive step under Article 29-2 (Appeal 2017-137961). A lawsuit for revocation was filed before the IPHC (Hei 31 Gyo-ke 10011) in February 2020, are explained below.

The reasons for rejection were prior art effect rejection.
adapting the length of tracr sequence “9 or more” should be regarded as an effect exceeding the expectations of a person skilled in the art, since there were no science papers or patent documents available at the time of the priority date disclosing that CRISPR-Cas9 system were applicable to eukaryotic cells.

As a result of the IPHC decision, the case was brought back to the JPO appeal board and then patented by the JPO appeal board as JP6723094.

Patent pool

The foregoing relates to foundational patents on CRISPR-Cas9 technology. Subsequently, as in many other countries, a considerable number of patent applications have been filed in Japan concerning CRISPR-Cas9 technology. If any person wishes to apply CRISPR-Cas9 technology to pharmaceutical developments etc., it will be necessary to use not only the foundational concepts but also a number of improved techniques. This means that it will be necessary to obtain licenses from many patentees, which is likely to be both time consuming and costly. Under such circumstances, use of a patent pool system that facilitates collectively obtaining licenses for patents relating to CRISPR-Cas9 technology has attracted attention. One example is that MPEG LA in the US has begun calling for participation in the patent pool for CRISPR-Cas9 technology. However, license situation remains opaque, and to achieve success a considerable number of obstacles will need to be resolved and overcome.

Technological developments in Japan

Although Japan does not hold an initiative in gene editing technology, many groups are actively conducting research and development. For example, Medalis Therapeutics Corporation (formerly EdiGENE, a venture to develop pharmaceuticals using CRISPR-Cas9 technology) has developed new platforms: CRISPR-GNMD (Guide Nucleotide Directed Modulation) that is effective for the development of efficacious therapeutics for hereditary genetic diseases.2

As noted above, since both the foundational patents of Broad etc. and UC etc. relating Cas9 in the Claims, use of other Cas polypeptides may not infringe the patents. Prof. Tomoji Mashimo et al. of Osaka University developed an E. coli - derived Ty-pil-ECRISPR system (CRISPR-Cas9) and found that the system is more efficient in gene editing than Cas9 system, with no prominent off-target effects.3 To confirm the therapeutic potential of the system, the group carried out Cas9-based repair of the DMD gene in induced pluripotent stem cells from a patient with Duchenne muscular dystrophy.

Target-AID invented by Prof. Kei Nishida et al. of Kobe University is a gene editing technique that introduces mutations by transforming nucleotides without cutting DNA.4 New gene editing tools are being developed in Japan.

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Target-AID invented by Prof. Kei Nishida et al. of Kobe University is a gene editing technique that introduces mutations by transforming nucleotides without cutting DNA. New gene editing tools are being developed in Japan.

A number of obstacles will need to be resolved.

The new agreement between the United States, Mexico, and Canada, came into force as of 1 July 2020. The USMCA is one of the most complex and complete agreements that these three countries have ever negotiated. This agreement replaced the North American Free Trade Agreement (NAFTA) that had been in place since 1 January 1994.

The year 1994 marked the beginning of a process of regional integration of the countries of North America, Canada, Mexico, and the United States had subscribed to NAFTA, the main objective of which was to create a free trade area and eliminate several product tariffs. NAFTA incorporated the regulation of goods, services, IP rights, and provisions to safeguard investment in the three countries.

NAFTA and the agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which was negotiated at the same time, were paramount for Mexico in terms of IP rights. In the 90s, during the NAFTA and TRIPS negotiations, a new regulation for industrial property was introduced in Mexico in order to meet commitments with its commercial partners. Of the three countries, Mexico had to make the most changes to its local regulation with significant changes in the patent field. Changes were positive and included granting protection for a broader range of inventions, including pharmaceuticals, and extension of patent protection period to 20 years.

Intimate economic ties had been developed between the three countries after NAFTA came into force. Trading volume had been significant. Every day, the United States conducted more than US $3.6 billion in trade with Mexico and Canada. From 1997 to 2017, trade under NAFTA increased almost four times, which allowed companies in the region to take advantage of

The impact of the United States, Mexico, and Canada Agreement (USMCA) on the Pharmaceutical industry: patent rights and test data exclusivity

Marina Hurtado-Cruz, Partner at Baker McKenzie and Head of the Patent Practice in Mexico, discusses the life sciences impact of USMCA.
the elimination of tariffs, save costs, have protection of their investments under a system of rights and dispute settlement, and in turn become more competitive.

Over the years, NAFTA began to lose competitiveness in the face of the economic reality of the North American region. There was a need to modernize and update the agreement to make it more consistent with the new economic situation and include cutting-edge elements in terms of a new generation of trade agreements. The reason behind modernizing NAFTA is to strengthen trade relations in the region and to become more competitive against other economic integration phenomena, particularly those that have been developing in Asia.

Thus, in 2017, the United States decided to renegotiate NAFTA because of a campaign promise of the Donald Trump administration. After more than 13 months of negotiation, the new agreement was signed by the parties during the G20 Summit that took place in Buenos Aires, Argentina, at the end of 2018. USMCA reinforces regulatory systems, E-commerce, and the protection of IP rights. It will affect a number of sectors, healthcare being one of them. Within the healthcare industry, patents and test data exclusivity protection were among the most controversial topics during the negotiations.

The most relevant issues regarding patents and test data exclusivity are the following:

**Patents**

Patents are an indispensable tool for the protection of inventions and the investments that go into them. Therefore, strengthening the protection and enforcement of IP rights, including patents, was a priority during the USMCA negotiations. The USMCA states that the three countries shall process patent applications in an efficient and timely manner, avoiding unreasonable or unnecessary delays. Furthermore, each country will make available patent term adjustment procedures when the pharmaceutical product is protected by a patent to compensate the patent owner for unreasonable delays in obtaining marketing authorization that affect patent rights.

This has been a sensitive issue for Mexico since the responsible authorities in the country have shown some resistance to establishing procedures to correct patent validity terms. In Mexican legislation, patent protection is granted for a non-renewable term of 20 years starting from the date on which the application is filed. Although under the USMCA the parties are obliged to compensate for unreasonable delays, in practice, this is not a relevant issue for IMPI. This is because during the negotiations of the USMCA, IMPI issued internal guidelines for examiners stating that the resolution of a patent procedure should not take more than 5 years from the filing date.

This provision included in IMPI’s internal guidelines was further confirmed in the New Mexican Industrial Property Law that was published in July 2020 and will become effective in November 2020. However, in this new law, the obligation to compensate pharmaceutical patent terms for unreasonable delays in the issuance of a marketing authorization was not included. In the case of Canada, a patent term restoration for up to two years was only implemented for the first time in 2017. This was not for all patents, only for some patents related to human and veterinary drugs. The United States did not need to make any changes to its legislation to comply with this requirement.

In addition to the foregoing, the New Mexican Industrial Property Law recognizes that new uses can be patented. Although in practice IMPI already grant protection for new uses, there is now greater legal certainty for their protection.

Furthermore, USMCA establishes that parties shall maintain a regulatory review exception for pharmaceutical products that permits a third person to make, use, sell, offer to sell, or import a product covered by a patent solely for the purposes to generate information to request a marketing authorization. This provision was also included in the new law approved last month by Mexico.

The USMCA asserts that patents shall be available for any invention, whether a product or process, in all fields of technology, provided that it is new. It has an inventive step and industrial application. In addition, and in contrast with NAFTA, USMCA expresses that inventions derived from plants can be subject to protection. This has the objective of increasing protection for plant-derived inventions and provide legal certainty; because even though these inventions were already granted in the region, this provision was not included in local regulations, like in Mexico. Finally, in the final version of the USMCA, a section outlining the exclusions from patentability was eliminated, the purpose of which was to strengthen the protection of a broader range of inventions, as long as they comply with the other cited requirements.

Recognizing the benefits of transparency in the patent system, the USMCA endeavors to publish pending patent applications promptly after the expiration of 18 months from the filing date or, if priority is claimed, from the earliest priority date. In order to comply with this requirement, Mexico amended its law in 2018 to allow the publication of complete patent files. Before this reform, the complete file was only made public after the patent was granted.

Many of the obligations established by the USMCA in patent matters, were implemented by Mexico in 2018, during the negotiations of the agreement. Some others, such as compensation for patent terms as a result of delay, and the regulatory review exception for pharmaceutical products were included in the New Mexican Industrial Property Law that came into force in July 2020. For some other cases, the USMCA establishes certain transition periods.

**Test data exclusivity**

As previously mentioned, to market a pharmaceutical product, it is necessary to obtain a marketing authorization, for which the applicant of an innovative product must present undisclosed information regarding the efficacy and safety of the same. Protection is the exclusivity period in which third parties cannot rely on or use information from the innovator to market the same product.

The original text of the USMCA signed by the parties in 2018 included a ten years protection term for biologics, which exceeded the...
available protection under both Canada and Mexico’s domestic regimes. In United States law however, there was already a 12-year protection term. Biologics were defined by the USMCA as “a product that is produced using biotechnology processes and that is, or alternatively, contains, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, for use in human beings for the prevention, treatment, cure or disease or condition.” Considering that production of biologics is costly, and protection of biologics through patent rights is limited, data protection is an important means for maintaining exclusivity and recovering the investment in time and resources.

In addition to biologics, further provisions, such as a protection period of at least three years with respect to new clinical trial information for new indications or formulations, and at least 5 years for new pharmaceutical products that contain a chemical entity that was not previously approved, were included in the original text of the agreement. This certainly was good news for innovators.

Interestingly, USMCA was amended in December 2019 in order to update several sections. The pharmaceutical industry had the most significant impact. The protection of biologics and new uses and methods were eliminated from the agreement as a result of pressure from democrats in the United States who argued that longer protection terms may raise prescription drug prices for patients.

In the case of Mexico, there is currently no local law or secondary regulation providing data exclusivity for biologics. In fact, NAFTA granted such protection for a period of no less than 5 years from the regulatory approval of pharmaceutical products. This protection for both small molecule drugs and biologics could only be obtained through litigation. The original text of the USMCA signed in 2018 would have provided legal certainty regarding the protection of data exclusivity. However, the protection of data exclusivity in the final version of the USMCA was restricted to at least 5 years for new pharmaceutical products and new chemical entities, which include biologics, similar to the protection already granted by NAFTA. Like Mexico, there is no local law or secondary regulation in Canada providing data exclusivity specifically for biologics. Canada currently has an 8-year data protection term for pharmaceutical products that contain new chemical entities, and biologics.

Conclusions & keynotes
The USMCA has provisions that impact many sectors, pharmaceutical being one of them. Among the relevant takeaways are the following:
• Like NAFTA, the USMCA states that the parties shall provide patent term adjustment proceedings to compensate patent owners from unreasonable delays of the patent offices to issue a patent in all fields of technology. In addition, for pharmaceutical products, another patent term adjustment shall be provided to compensate unreasonable delays of the health authorities to grant marketing approval.
• Members shall provide patent regulatory review exceptions to make, use, sell, offer to sell, or import a product covered by a patent for the purpose of requesting a marketing authorization.
• --Also, in the patent field, patents shall be available for any invention, whether a product or process, in all fields of technology, provided that it is new, it has an inventive step and industrial application. In addition, and in contrast with NAFTA, the USMCA states that inventions derived from plants can be subject to protection.

Although there were considerable changes in the version of the USMCA originally signed in 2018 in contrast with the amendments approved in 2019, which affect mainly the protection of clinical data, there are positive changes in the field of patents that may create a balance and benefit pharmaceutical patent owners. Furthermore, although some data protection provisions were eliminated from the USMCA, protection may be granted or increased locally in each of the countries. In Mexico, for example, local pharmaceutical associations will seek to increase test data protection for biologists. Without a doubt, of the three countries, Mexico is the one that has had to and will continue to implement the greatest number of changes to make its local legislation comply with the USMCA obligations, followed by Canada. The United States will not have to make relevant changes.

Contact
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The PPB has been a very useful tool in accelerating the granting of patents in Mexico.
The following medical applications have been described for Cannabis:

**THC**
- Analgesic
- Anti-bacterial
- Anti-cancer
- Anti-inflammatory
- Anti-spasmodic
- Appetite Stimulant
- Bronchodilator
- Neuroprotective

**THCV**
- Anti-convulsive
- Appetite Suppressor
- Bone Stimulant

**CBD**
- Analgesic
- Anti-anxiety
- Anti-bacterial
- Anti-cancer
- Anti-convulsive
- Anti-depressant
- Anti-epileptic
- Anti-inflammatory
- Anti-insomnia
- Anti-ischemic
- Anti-psychotic

### Industrial uses

**THC**
- Anti-spasmodic
- Bone Stimulant
- Immunosuppressive
- Neuroprotective

**CBDV**
- Anti-convulsive
- Bone Stimulant

**CBC**
- Analgesic
- Anti-bacterial
- Anti-cancer
- Anti-depressant
- Anti-fungal
- Anti-inflammatory
- Anti-insomnia
- Bone Stimulant

**CBG**
- Analgesic
- Anti-bacterial
- Anti-cancer
- Anti-depressant
- Anti-fungal
- Bone Stimulant

### Uses of cannabis

Recent reports indicate that Cannabis production is increasing and that cannabinoid formulations have been changing over the last two decades, especially with regard to their THC and CBD concentrations.

### Therapeutic applications of Cannabis and cannabinoids

THC is the psychoactive principle of Cannabis, inducing the Cannabis inebriation sought by many users. Its addictive potential and negative consequences are now well known. The effects of CBD are distinct and, in many cases, the opposite of THC's effects. CBD seems not to induce euphoria and seems to have anti-psychotic, anxiolytic, antiepileptic, and anti-inflammatory properties.

According to an evaluation (in 1999) by the Institute of Medicine in the United States, on Cannabis as a medication, the future of medical Cannabis lies in isolating its cannabinoid components and their synthetic derivatives. The variable composition within the raw Cannabis plant and especially the differing THC/CBD ratios make therapeutic applications of these products quite complex.

This would, in turn, motivate research, health, industrial, and economical advancement, improving the quality of life for hundreds of patients.

### The future of medical Cannabis lies in isolating its cannabinoid components.

#### Résumé

Janett Lumbreras - Senior Associate, Uhthoff

Janett has a Pharmaceutical Chemistry-Biology Degree from UNAM. Diplomas in Access to Worldwide Scientific and Technological Information and in Industrial and Intellectual Property law from UNAM. She is a Senior Associate at Uhthoff, working with patent matters for more than 20 years. She is an active member of AMPPI, AIPLA and CONSEP.
interest. Others are aiming to modify chemical synthesis in the Cannabis plant by genetically altering its cells to make the desired molecules from shoot to tip, thereby boosting yield.

US patent application No. 16/594,733 discloses a method of generating and selecting mutant new varieties of Cannabis plants through chemical mutagenesis of Cannabis cell suspensions.

Benefits of microbial synthesis include the ability to mass-produce rare cannabinoids that are usually present in plants only in trace amounts or even molecules not found in nature. Transgenic plants can also be engineered for improved production of secondary metabolites, doubling can include larger organs and more particularly the use of these alleles to produce Cannabis plants having very high ratios of CBGAs to CBDAs and/or THCa.

Examples of filed PCT applications referred to improvement of Cannabis production are cited hereinbelow.

Applications filed according to IPC Code

Table: Number of applications by Publication Date

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<thead>
<tr>
<th>No.</th>
<th>No. MX Publication</th>
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<td>MX/a/2019/015673</td>
<td>Veterinary granules composition containing hemp extract</td>
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<td>2</td>
<td>MX/a/2019/015636</td>
<td>Sleep disorder compositions and treatments thereof</td>
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<td>3</td>
<td>MX/a/2019/014765</td>
<td>Use of cannabinoid in the treatment of fibrous sclerosis complex</td>
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<td>MX/a/2019/016050</td>
<td>Cannabidiol extraction process using brine</td>
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<td>5</td>
<td>MX/a/2019/010078</td>
<td>Method and cell line for production of phytocannabinoids and phytocannabinoid analogues in yeast</td>
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<td>MX/a/2019/010183</td>
<td>Process for purification and separation of cannabinoids from dried hemp and Cannabis leaves</td>
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<td>Cannabis fiber, absorbent cellulose structures containing Cannabis fiber and methods of making the same</td>
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<td>MX/a/2019/010481</td>
<td>Methods and apparatus for low-pressure radiant energy processing of Cannabis</td>
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<td>9</td>
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<td>Pat. MX 50278 B Cannabis fiber, absorbent cellulose structures containing Cannabis fiber and methods of making the same</td>
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<td>MX/a/2019/002963</td>
<td>Trichome specific promoters for the manipulation of cannabinoids and other compounds in glandular trichomes</td>
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<td>MX/a/2019/002968</td>
<td>Plants and methods for increasing and decreasing synthesis of cannabinoids</td>
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<td>New Cannabis tablet formulations and compositions and methods of making the same</td>
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<td>13</td>
<td>MX/a/2014/003160</td>
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<td>Cannabis plants having modified expression of THCA synthase</td>
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<td>18</td>
<td>MX/a/2014/006936</td>
<td>Pat. MX 43013 B Genes and proteins for alkaloids-CoA synthesis</td>
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<td>19</td>
<td>MX/a/2015/003202</td>
<td>Breeding, production, processing and use of specialty Cannabis</td>
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</table>

In Mexico there have been few patents granted, but there are several patent applications pending to be examined. These cases involve all the fields related with Cannabis. It should be noted that during 2019 the number of applications increased.
CANNABIS

The following Variety Plants of Cannabis has been filed at UPOV.

Applications filed by Country

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Applications filed according to UPOV Code

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<td>Cannabis sativa subsp. indica</td>
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</tbody>
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Number of applications by Filing Date

This graph shows how the number of applications associated to Cannabis is growing; the significant increase during 2019 is notable.

Conclusions

Known uses of Cannabis and new medical and industrial uses thereof have raised an interest to improve Cannabis production to increase industrial-scale production of cannabinoids. The use of different methods has allowed for these improvements. The methods include, for example, genetic modifications, cultivation methods that increase the content of the substance in interest (CBD), and obtaining plant varieties. It follows that new technologies developed in order to achieve such objectives need to be protected through patents, plant varieties, or any other industrial property rights.

Furthermore, due to the nature and psychoactive effects of Cannabis, there is the need of domestic regulations for the production, use, and marketing of Cannabis for medical and industrial uses.

In recent years, the number of patent applications related to Cannabis around the world has grown significantly and will continue increasing as legal frameworks progress in each country. The research and development of new applications of Cannabis will promote such increase. It is also expected for other ways of protection to increase, e.g. Plant Variety, or Seed Certification.

In Mexico, the legalization for the use of Cannabis sativa for medicinal and research purposes has been approved. The laws regarding this subject-matter will apply to the following activities:

I. The sowing, harvesting, production, transportation, distribution, marketing, carrying, and consumption of Cannabis and its derivatives for personal, therapeutic, and scientific purposes.

II. Public Health control of Cannabis

In consequence, Universities, Research Centers, and Pharmaceutical Companies will now be able to do research on Cannabis sativa.

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Conclusion

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