The Life Sciences Lawyer

Issue 7

GLOBAL REACH, LOCAL KNOWLEDGE

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Objective comments on the patent litigation case of Ticagrelor Crystalline Form in China

Tang Xiaofeng, Patent Attorney at Beijing Geach Intellectual Property Law Office, examines the case of the invalidated Ticagrelor crystalline form patent CN200610002509.5 of AstraZeneca, explaining why he believes the patent should in fact be maintained.

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CTC Legal Media

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THE LIFE SCIENCES LAWYER
Issue 7

Editor
Faye Waterford
faye@ctclegalmedia.com

Publishing Director
Chris Dooley
chris@ctclegalmedia.com

Advertising Enquiries
Katie Kerr (Publishing Executive)
katie@ctclegalmedia.com

Subscription Enquiries
subscriptions@ctclegalmedia.com

Accounts Enquiries
accounts@ctclegalmedia.com

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Tel: +44 (0)20 7112 8862
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CTC Legal Media

Editor's welcome

Our cover story this issue brings you an evaluation of the Ticagrelor Crystalline Form patent litigation case in China, with objective comments from the author, Tang Xiaofeng, as to why he believes that the compound in question should in fact be patentable due to its innovative qualities despite the court's decision.

This issue also includes an evaluation of the TRPIS waiver from Norton Full Bright, questioning how the TRIPS Waiver relates to trade secrets and technology transfer with advice for life sciences companies. And an article explaining the main applications of CRISPR in patent protection of technologies in the field, covering hot topics such as oncology, diagnostics, stem cells, primary cells, CRISPR animal models and more. Both topics have been spurred on by the COVID-19 pandemic.

> **"Both topics have been spurred on by the COVID-19 pandemic."**

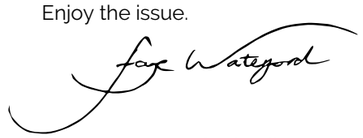
Further, Polsinelli explores march-in rights and their possible resurgence over the Bayh-Dole Act after rising concerns surrounding drug pricing. Could federal policy be shifting? Find out when march-in action is necessary.

Plus, a 360 degree overview of the intellectual property available to protect innovation in the life sciences sector, reviewing the use of patents, trademarks, trade secrets, and domain names.

We also have a review of the first impacts that the ADI 5,529 judgement in Brazil one year on from its implementation, relating to pharmaceutical patents. Has the implementation been successful?

Our next issue of *The Life Sciences Lawyer* will be published in early 2023, is there a topic you would like to see covered? Contact us now to let us know.

Enjoy the issue.



Faye Waterford, 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.

Issue 7

Contents

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Résumé

Tang Xiaofeng, Attorney-at-Law/ Patent Attorney

Tang specializes in patent litigation, patent invalidation and patent prosecution strategy, covering various technical fields such as pharmaceutical chemistry, formulation, biotechnology, and polymer.

He is good at solving inventiveness issues and insufficient disclosure issues and is skilled in obtaining patent rights and defending patents against invalidation attacks.

He has been engaged as a pharmaceutical patent agent for nearly 30 years handling more than 2500 patent applications at home and abroad, and easily recognizes examiner's errors. He is familiar with inventive examination standards in US, EPO and JP, and easily communicates with foreign patent lawyers.

Tang Xiaofeng

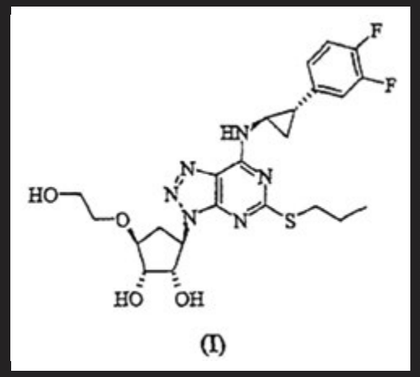
Ticagrelor crystalline form patent CN200610002509.5 of AstraZeneca was declared to be invalidated for lack of inventiveness by the China National Intellectual Property Administration (CNIPA), (No.33975). After that, Beijing Intellectual Property Court made an administrative judgment upholding the invalidation decision of CNIPA and then The Intellectual Property Court of the Supreme People's Court of China (SPC), (2019) SPC IP Admin. Final 33 upheld first-instance judgment. The case was selected by SPC as a typical case to the United Nations Conference on Trade and Development because it established the standard that the supplementary experimental data submitted by a patent applicant after the filing date may be accepted.

However, the author considers that the invention is inventive and the patent should be maintained valid.

Case Summary

The granted claim 1

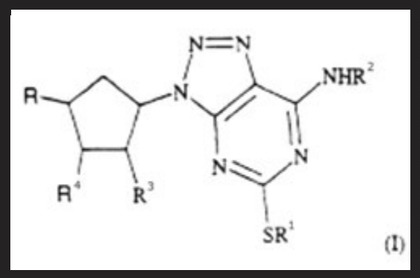
1. A compound of formula (I) in crystalline form II:



(I)

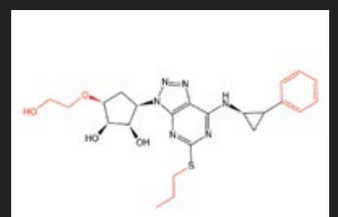
wherein the X-ray powder diffraction pattern is basically shown in Figure 1.2.

Evidence 6WO09905143 disclosed a triazolo [4.5-d] pyrimidine compound as a P2T receptor antagonist:

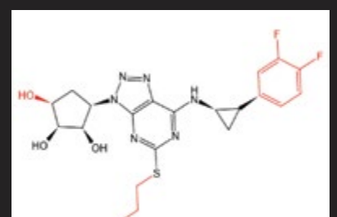


(I)

wherein Examples 32 and 68 respectively disclose specific compounds with the following structural formula:



Compound of example 32 in Evidence 6

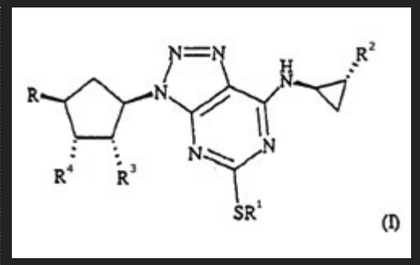


Compound of example 68 in Evidence 6

Evidence 4: organic chemistry experiment.

Evidence 3 (WO0034283A1) is the Ticagrelor compound patent, wherein the compound prepared in example 3 is the compound itself protected by claim 1 of the disputed patent (regardless of crystalline form),

> **“However, the author considers that the invention is inventive and the patent should be maintained valid.”**



(I)

Wherein:

R^2 is a phenyl group, optionally substituted by one or more fluorine atoms;

R is XOH, where X is CH, OCH_2CH_2 or a bond;

provided that:

1. when X is CH_2 or a bond, R1 is not propyl.

2. when X is OCH_2CH_2 and R1 is propyl, the phenyl group at R^2 must be substituted by fluorine.

CNIPA considered that the compound of example 68 in evidence 6 was actually covered by the compounds of general formula (I) defined in evidence 3, that is, what the patentee wants to prove is equivalent to that of a specific compound within the scope of general formula (I) has better technical effect than another specific compound. This actually constitutes a “selective invention”. Moreover, such information cannot be obtained by those skilled in the art by reading evidence 3.

This means that the compound of example 3 in evidence 3 must have unexpected technical effects relative to the compound of an example in evidence 6 before its inventiveness can be recognized. The patentee uses the supplementary experimental data in counterevidence 2 and counterevidence 5 to prove that the patented compound has unexpected technical effects relative to evidence 6. So the SPC established the standard below at the first time for accepting supplementary experimental data by CNIPA.

The SPC’s viewpoints in its judgment

1. Conditions for accepting supplementary experimental data submitted by the patent applicant after the filing date

Firstly, the original patent application documents shall clearly describe or implicitly disclose the to-be-confirmed fact that is intended to be directly proved by supplementary experimental data, and this is a positive requirement.

Second, the applicant cannot remedy the deficiencies inherently and naturally present in the original patent application documents by the supplementary experimental data, and this is a negative requirement.

Although the metabolic stability of the compound of claim 1 is better than that of example 32 of evidence 6, it cannot be determined that the better effect of the compound of claim 1 in terms of metabolic stability reaches a degree unexpected to those skilled in the art.

2. Determination of the inventiveness of the compound of claim 1

Either of the distinguishing technical features of the compound of claim 1 from the compound of example 32 of evidence 6 lies in that the right benzene ring of the compound of claim 1 has a 3,4-difluoro substituent, while the right benzene ring of the compound of evidence 6 has no substituent. Example 68 of evidence 6 gives a clear teaching that there is a 3,4-difluoro substituent on the right benzene ring of a similar compound. Those skilled in the art are motivated to introduce the 3,4-difluoro substituent on the right phenyl of the compound of example 32 of evidence 6 to obtain the compound of claim 1. Therefore, the compound structure of claim 1 possesses no inventiveness.

3. Determination of the inventiveness of the crystalline form of the compound in claim 1

Evidence 4 is a textbook involving organic chemistry experiments. The compound crystalline form II claimed in claim 1 is obtained by the specific crystallization method of example 2. The solvent chloroform used in the method is a common solvent in the preparation of crystalline form compounds. The solvent has also been disclosed in evidence 4, and the specific operation procedure used in this method is also a conventional technical means for preparing crystalline compounds. Therefore, the crystalline form II of the compound of claim 1 possesses no inventiveness over evidence 6 in combination with evidence 4.

Three comments on inventiveness

1. Error in applicable law

The invalidation decision and the final judgment do not discuss the applicable law, but directly use the three-step approach to evaluate inventiveness.

The examination of this patent shall be governed by the patent law 1992 and the Patent Examination Guideline 1993 rather than 2001 or 2006.

There was no three-step approach in the guideline 1993 for assessing inventiveness, but only for the non-obviousness concept. There is a special provision for the assessment of inventiveness of a compound, which mainly depends on whether the structure of a compound is close to that of a known compound. A novel compound that is not close to the known compound in structure and has certain use or effect can be considered to be inventive without being required to have unexpected use or effect; whereas the compounds close to the known compounds in structure must have unexpected use or effect. Evidence of technical effect may be submitted after the filing date. The author had already engaged in patent prosecution then and witnessed that practice.

> **“In addition, R and R^2 in evidence 6 are correlated technical features.”**

The compound crystalline form II of claim 1 differ from the compound of example 32 in not only 3,4-difluoro substituent on the right benzene ring of the compound of claim 1,but also crystalline form II structure. Clearly, the crystalline form of the compound in claim 1 is not close to the structure of the compound in example 32 of evidence 6, has novelty, and has certain therapeutic effect (P2T- antagonist activity). Its inventiveness should be recognized without requiring the patent to have unexpected effects.

In addition, the counter evidence 5 submitted by the patentee in the invalidation procedure is also sufficient to prove the excellent technical effect described in the patent specification. Counter evidence 5 makes a comparative test on the compound of example 3 in the U.S. family patent US6525060 of evidence 3 and the compounds of examples 32 and 68 in the U.S. family patent US6251910 of evidence 6. Among three indicators, example 3 of evidence 3 is better than example 32 of evidence 6 and thus example 3 has better technical effect. This also shows that the compound described in this patent is inventive over evidence 6, and the crystalline form of the compound in this patent is naturally inventive relative to compound 32 in evidence 6.

It is worth mentioning that during the substantive examination stage, evidence 3 was allowed over right evidence 6 (CN1270590) according to the examination practice at that time. This shows that according to the then standards, evidence 3 is inventive over evidence 6. Although the patent of evidence 3 has expired, evidence 3 was validated prior to expiration, so the crystalline form II of the compound of claim 1 also has inventiveness over evidence 6.

2. Error in application of law

Even according to the guidelines 2001 or 2006, this patent is inventive.

First, the fact finding in the invalidation decision that the compound of example 68 in evidence 6 is actually covered by the compound of general formula (I) defined in evidence 3 is wrong.

In fact, example 32 and example 68 in evidence 6 have been excluded by evidence 3 (condition

3 and condition 1 in its claim 1). Condition 1 of claim 1 of evidence 3 states: when x is a bond, that is, R is-OH, R1 is not propyl, i.e., example 68 of evidence 6 is not tenable (excluded from evidence 3); Condition 3 of evidence 3 excludes the compound of example 32 of evidence 6; Both compounds of examples 68 and 32 of evidence 6 are preferred compounds of evidence 6, but both are excluded from evidence 3. Therefore, a specific compound within the scope of general formula (I) of evidence 3 (such as the compound of example 3) is not the so-called "selective invention" relative to other compounds of evidence 3. That is, in order for the compound of example 3 of evidence 3 to be inventive relative to evidence 6, it is not necessary to require that the compound of the patent has unexpected technical effects relative to the compound of example 32 or 68 of evidence 6.

Moreover, the inventiveness of the compound (and its crystalline form) of claim 1 of the patent relative to evidence 6 lies mainly in its non-obviousness rather than unexpected technical effect.

Contrary to the finding of the invalidation decision and final judgment, since it is recognized that the metabolic stability of the compound of claim 1 is better than that of example 32 of evidence 6, the technical problem actually solved by claim 1 of the patent relative to example 32 of evidence 6 should be to provide an active crystalline compound with excellent metabolic stability for easy operation and processing. It is apparent that there is no technical indication in evidence 6 that the group of example 68 replaces the group of example 32 to improve the stability. Therefore, the compound of claim 1 is non-obvious.

In addition, R and R^2 in evidence 6 are correlated technical features. Without hindsight, a skilled person will not arrive at the compound of example 3 of evidence 3 from the replacement of the technical feature of the compounds of two specific examples in evidence 6, let alone the crystalline form II of the compound. The metabolic stability of the compound of the claim 1 proved by the supplementary experimental data is better than that of example 32 of evidence 6, which exceeds the reasonable expectation of those skilled in the art that they might have the same or inferior level of efficacy.

3. Evaluating the inventiveness of the crystalline form of the compound of claim 1 of the patent

The general description and 114 examples of evidence 6 do not mention crystallization or crystalline form. The purpose of evidence 6 is to provide antithrombotic drug compounds without involving the problem of crystalline forms. Evidence 4 refers to the method of re-crystallization and purification with various solvents, which does not involve the crystallization of antithrombotic drug compounds. There is no technical enlightenment in the prior art about directly preparing new compounds and new crystalline forms at the same time from evidence 6. Evidence 3 (including the compound of its example 3) has not been disclosed at the priority date of this patent. In the absence of the compound, a skilled person will not think deliberately of preparing the crystal form II of the compound from the virtual compound of example 3 of evidence 3 according to a particular solvent and specific method of evidence 4. Therefore, the crystalline form II of the compound of claim 1 is non-obvious over evidence 6 even in combination with evidence 4.

> **Even according to the guidelines 2001 or 2006, this patent is inventive.**

To sum up, the author believes that the invalidation decision and the final judgment have errors in determining the facts and applying laws and regulations, which are not persuasive; If the patentee would have stated the above reasons and questioned the invalidation decision and the viewpoints of the judges, they were able to overturn the judgment conclusion, safeguard their rights and promote the right implementation of the patent law.

Contact

Beijing Geach Intellectual Property Law Office
Room 525, Building B, Fucheng Mansion
No. 98 Beilishi Street Jia, Xicheng District
Beijing 100037, P. R. China
Tel: +86-10-68318129
tang@geach.com.cn
www.geach.com.cn

First impacts of the judgment of ADI 5,529 in the Brazilian patent scenario from the perspective of pharmaceutical patents

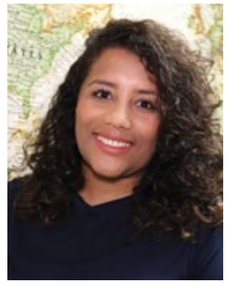
Mônica Gurvitz and Julia Fernandes, Partners at Montaury Pimenta, Machado & Vieira de Mello, evaluate the implementation of the ADI 5,529 one year on.

Almost one year ago, the Brazilian Supreme Court has finally judged the lawsuit that challenged the constitutionality of the sole paragraph of article 40 of the Brazilian IP Law (ADI 5,529). ADI 5,529 was filed in 2016 but its judgment was being postponed over and over until April 2021, when the subject got a lot of attention in view of the possible impacts thereof in the fight against the COVID-19 pandemic in Brazil. Then, last May, the lawsuit has finally been decided and now, one year later, it might be interesting to analyze what has happened due to this decision so far. However, in order to understand the current situation, it is necessary to, at first, understand the provision of the Brazilian IP Law that was challenged by the lawsuit as well as the situation of the patent examination in Brazil by then.

According to the *caput* of Article 40 of the Brazilian IP Law, a patent is valid for 20 years and a utility model for 15 years, counted from its filing date. In addition, the sole paragraph of this article established a minimum validity term of 10 years for patents and seven years for utility models, counted from the grant date, for cases granted more than 10 years after their filing dates. This provision was compensation to the patentees for the excessive delay of the Brazilian Patent Office (BRPTO) in examining and granting patents.

However, this paragraph, which should be exceptionally used, has become the rule in the last years, due to the delay in the technical examination of patents and, therefore, the patent expiration date in Brazil was mostly subject to its granting date. In most technical fields, including the pharmaceutical one, the patent examination could take more than 10 years, in 2016, when the lawsuit was filed.

Mônica Gurvitz



Julia Fernandes

Although the number of years to have a pharmaceutical patent granted was already being reduced due to the BRPTO successful Backlog Elimination Plan, in 2021, almost 70% of the patents covering medicaments, in force at that moment, benefited from the sole paragraph of Article 40 of the Brazilian IP Law. According to those who were against this law provision, this provision unduly extended the patents' validity and also generated legal insecurity, as they argue it was not possible to foresee the precise patent expiration date of patents in Brazil. Specifically in the pharmaceutical field, this could jeopardize the entrance of generic drugs in the market.

Considering this scenario, in May 2021, the Brazilian Supreme Court decided on the unconstitutionality of the sole paragraph of Article 40 of the Brazilian IP Law. Consequently, all patents granted from that date on are valid for a 20-year term, counted from their filing date, in accordance with the provisions of the *caput* of this article.

This decision affected almost 9,000 patent applications of all technological fields, which were waiting for a final decision in the first instance for more than 10 years. Among them, around 200 applications could be granted already expired. Additionally, a specific group of valid patents which had their validity term established based on the 10-year rule was retroactively affected.

Driven by the pandemic emergency, the Brazilian Supreme Court decided for the retroactive *(ex tunc)* application of the unconstitutionality of the sole paragraph of Article 40 for patents related to pharmaceutical products and processes, and equipment and/or materials for use in healthcare. However, it was up to the BRPTO to select which patents already granted

should have the validity adjusted.

For such selection, the BRPTO used some criteria, such as the prior consent of the National Health Surveillance Agency (ANVISA) and certain IPC classifications. In the first Official Bulletin after the Supreme Court's decision, a first list with 3,341 patents that had their validity changed was published and in total, around 7,000 patents were affected. In other words, practically overnight, thousands of patents have lost years of validity, and some technologies have even become part of the public domain. Companies holding the technologies faced an unexpected scenario of loss of market exclusivity and uncertainty. On the other hand, it is a mistake to believe that this scenario brought surprise and uncertainty only to patentees.

As soon as the patents were republished with their validity changed, the patentees began to file lawsuits requiring adjustments to the expiration dates (PTA's – Patent Term Adjustments), based on an excerpt from the vote of the Rapporteur Minister Dias Toffoli, which mentions the use of PTA's in certain cases of delayed examination. In general, said lawsuits require the settlement of an adjusted validity, adding some years to the current term based on the disproportionate and unjustified delay of the BRPTO to analyze and grant patents. Until now, more than 30 PTA's lawsuits have already been filed before the Federal Courts.

It is important to mention this is the first time Patent Term Adjustments are required in Brazil. These Court Actions are very recent in the country and there is still no case law on the subject. So far, it is only possible to know that patentees are requesting validity extensions, some of them exceeding the original period of 10 years counted from the patent granting date. Furthermore, since each case took a different time to be examined, the number of years to be added to the validity varies on a case-by-case basis. As an immediate consequence, until the end of such Court Actions, it is not possible to predict, for instance, how it is going to be the situation for generics aiming at entering the Brazilian market.

> **Its judgment was being postponed over and over until April 2021, when the subject got a lot of attention in view of the possible impacts thereof in the fight against the COVID-19 pandemic in Brazil.**

Meanwhile, it is not possible to state that the retroactive effect of the decision on the sole paragraph of article 40 for pharmaceutical patents provided any benefit for the COVID-19 pandemic. As it is widely known, the success in the fight against the virus is the result of the massive vaccination campaigns and the patents or patent applications related to the vaccines used in said campaigns were not affected by said decision. As a matter of fact, before the judgment itself, BRPTO provided to the Courts information about how the change in the legislation could actually affect the patent applications related to COVID-19. According to the Institute, among the 90 patent applications that contained indication of possible use in the fight against COVID-19 that were pending decision, only four could possibly be granted based on the sole paragraph of Article 40.

In a nutshell, the *ex tunc* application of the decision has not result in any beneficial effect so far. In fact, it seems to create a scenario of legal uncertainty not only for patentees but also for generic drug companies. It is not possible to guarantee when the court actions directed to PTAs will be judged, nor the outcome of these judgments.

Ironically, the fight against the alleged legal uncertainty caused by the lack of definition in the validity of patents, which was exactly one of the major arguments used to defend the unconstitutionality of the sole paragraph, might have led to a much more indetermined scenario. Has it backfired?

Résumés

Mônica Gurvitz, Partner
Mônica holds a BSc in biomedical sciences from the Federal University of the State of Rio de Janeiro and a BSc in chemical engineering from the Federal University of Rio de Janeiro. She has been working with intellectual Property since 2016 and has concluded the Intellectual Property Rights Specialization Course at Pontificia Universidade Católica do Rio de Janeiro.

Julia Fernandes, Partner
Julia is a pharmacist graduated from the Federal University of Rio de Janeiro (UFRJ) and a pharmacy technician graduated from the Federal Institute of Science and Technology of Rio de Janeiro (IFRJ). She started her Intellectual Property career before graduating through an internship in one of the biggest offices in the country, working in the Patent Formalities Department.

Mônica and Julia advise their clients on a wide range of technical issues regarding patent prosecution, as well as performing prior art searches and drafting patents and freedom to operate reports, particularly in the chemical, pharmaceutical and biotechnology fields.

Contact

Montaury Pimenta, Machado & Vieira de Mello
Av. Almirante Barroso, 139,
7º andar, Centro, Rio de Janeiro,
Brasil, CEP . ZIP 20.031-005
Tel: +55 21 2524-0510
www.montaury.com.br

Will old Bayh-Dole be taught new tricks?

Dr. Rebecca McFadyen and Dr. Tara Nealey of Polsinelli review the original implementation of the Bayh-Dole Act and why there are now petitions to use either march-in or government use rights to remedy unjustifiable drug pricing.

The specter of the COVID pandemic renewed questions about whether and how the US federal government can act to make prescription drugs more affordable to the American public. Such questions have been central to a line of petitions since 1997, unsuccessfully appealing to the US government to exercise its march-in rights under the 1980 Bayh-Dole Act to impose prescription drug price controls in specific cases. Is it possible that after decades of rejecting the use of march-in rights, the winds of federal policy could possibly be shifting?

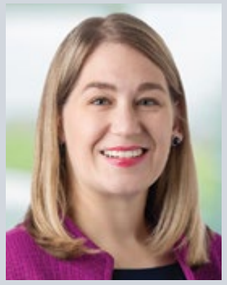
Before 1980, the US government did not have a uniform IP with respect to all the federal granting institutions that funded research, or technology transfer to the private sector. The only consistent rules were that the government retained title to inventions and would only license inventions nonexclusively. Federal agencies had collectively obtained over 28,000 patents, but out-licensed less than 5% of that number. In contrast, in cases in which private companies were allowed to retain title, companies successfully secured licenses for about 25% - 30% of those patents.[1] Some believed there was little to no incentive to commercialize inventions owned by the federal governments. Others found securing access to government-funded inventions to be an uncertain and confusing process.

[1] GAO Report to Congressional Committees, Technology Transfer – Administration of Bayh-Dole Act by Research Universities (May 1998), Report No. GAO/RCED-98-126, p. 3, available at https://www.gao.gov/assets/rced-98-126.pdf.

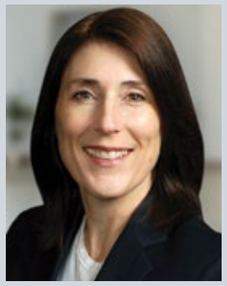
Résumés

Dr. Rebecca McFadyen, Counsel
A registered patent attorney with an advanced degree in biomedical sciences, Rebecca McFadyen focuses her practice on all aspects of domestic and international patent prosecution, including inventorship, noninfringement, and invalidity analyses, third-party preissuance submissions, client counseling, and pre-litigation analysis relating to the life sciences and biotechnology technical areas. She works with clients to review, analyze and evaluate intellectual property-related issues to provide a comprehensive overview of the portfolio.

Dr. Tara Nealey, Shareholder & Practice Chair
Dr. Tara Nealey chairs the Biotechnology and Life Sciences Patent Prosecution practice group. Bringing a background in academic physiology research, she focuses her practice on clients with intellectual property questions relating to the full range of life science technologies. Her experience encompasses over two decades of IP counsel to clients of all sizes, including individual inventors, public and private universities and research institutions, start-up companies, mid-size firms and Fortune 500 companies. Tara has extensive experience guiding clients through development of robust patent portfolios; guiding international patenting strategy; analyzing patent landscapes and key competitors' patents; preparing freedom-to-operate (non-infringement) and patent invalidity opinions; analyzing strengths and weaknesses of patent portfolios, and handling IP due diligence in mergers and acquisitions; and analyzing in- and out-licenses of patented technologies.



Dr. Rebecca McFadyen



Dr. Tara Nealey

> **Over the past decade or so, clear coalitions for and against the exercise of march-in rights as a means to control prescription drug prices have developed.**

Against this background, a bipartisan team of Senators Birch Bayh (D-Indiana) and Bob Dole (R- Kansas) introduced legislation to reform US patent policy related to government-sponsored research. In December 1980, President Carter signed the Bayh-Dole Act (P.L. 96-517, Patent and Trademark Act Amendments of 1980) into law. The Act established a new framework by which small businesses and non-profit institutions including universities could retain title to inventions developed under federally funded research programs and could commercialize federally funded inventions, and by which a private business could become an exclusive license for an agency's invention.

According to AUTM, "The Bayh-Dole Act fundamentally changed the nation's system of technology transfer by enabling universities to retain title to inventions and take the lead in patenting and licensing groundbreaking discoveries."[2] The Act has been assessed as "the most inspired piece of legislation to be enacted in America over the past half-century."[3] For 17 years, it was recognized as successful and remained uncontroversial, until in 1997, one of the Act's provisions was first used in an effort to control the price of a prescription drug.

Section 203 of the Act provides that when necessary, a federal agency that funded the research can require the contractor, assignee, or exclusive licensee to "grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances".[4] If the contractor, assignee, or exclusive licensee fails to grant a license, then the federal agency can grant a license to itself.

According to § 203, such march-in action by the US government is necessary when:

- the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
- it is necessary to alleviate health or safety needs that are not reasonably satisfied by the contractor, assignee, or licensee;
- it is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor; or
  the agreement required by § 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to § 204.

Over the past decade or so, clear coalitions for and against the exercise of march-in rights as a means to control prescription drug prices have developed. Supporters of exercising march-in rights assert that it is a wrongly overlooked and existing statutory mechanism for combatting high drug prices and ensuring that U.S. citizens enjoy the benefits of public R&D funding. Among proponents are patients, families, and organizations such as Knowledge Ecology International (KEI), the National Physicians Alliance (NPA), Public Citizen, Union for Affordable Cancer Treatment (UACT), and Universities Allied for Essential Medicines (UAEM). Others assert that march-in rights were never intended as such, and do not provide such a broad authority, but rather are narrowly limited to the four circumstances expressly identified in the statute. Another concern is that use of march-in rights would discourage private investment in the enormous cost and effort needed to bring treatments from early-stage research to the marketplace. Parties aligned against the use of march-in rights to address prescription drug pricing concerns include the Bayh-Dole Coalition made up of over 100 research foundations, life science organizations, lawyers, past-AUTM presidents, and others.

Yet, in the 40+ years since march-in rights were codified, no federal agency has actually exercised its march-in rights. From 1997 to 2016, the NIH has been petitioned at least six times to do so, in various efforts to get around patents controlled by a private company. In 1997, CellPro attempted to convince the US government to exercise march-in rights over a patent which covered CellPro's own FDA-approved product, but was owned by a government contractor. The NIH declined CellPro's petition essentially on the basis that it was unnecessary, noting that the contractor was making reasonable efforts to commercialize its invention. In 2004, the NIH was petitioned twice. Petitioners asked the NIH to intervene regarding Norvir/ritonavir, an HIV/AIDS treatment, and also regarding Xalatan/latanoprost, a glaucoma treatment, both on the basis of perceived excessively high pricing. In 2010, the NIH received a petition regarding Fabrazyme/agalsidase beta, used to treat Fabry disease, on the basis that the manufacturer was unable to manufacture the drug in sufficient amounts. These petitions were likewise declined, with the NIH taking the position that the drugs were being made reasonably available to the public. In 2012, a second petition was submitted for Norvir/ritonavir, more specifically supporting high price concerns by comparing the drug price in the US to its price in other wealthy nations. Importantly, the NIH declined specifically opining that such price differences were not sufficient to qualify a march-in as necessary.

> **Yet, in the 40+ years since march-in rights were codified, no federal agency has actually exercised its march-in rights.**

In January 2016, KEI and the UACT submitted a petition to the NIH, the Department of Defense (DoD), and the Department of Health and Human Services (HHS) requesting "to use its royalty-free rights in the relevant patents, or to grant this request for march-in rights," regarding the prostate cancer drug Xtandi/enzalutamide. The petition acknowledged that while "Xtandi is an expensive drug everywhere … the prices in the United States are far higher than any other country in the world, despite the fact that the critical research benefited from U.S. taxpayer funded grants from the NIH and DoD."[5] Six months later, the NIH rejected the KEI/UACT march-in petition and subsequently rejected an appeal.

In November 2021, the HHS received another march-in petition for Xtandi.[6] This petition noted, "[i]n the past, the use of march-in rights for enzalutamide has been supported by more than a dozen organizations and several members of Congress in both the U.S. Senate and the House of Representatives."[7] The petition also requested consideration by an impartial decision maker, noting:

Under two previous Administrations, HHS has been petitioned to grant a march-in request for the patents on enzalutamide. Each time HHS delegated the case to the NIH, and each time, including on the administrative appeals, such requests and appeals were summarily rejected, in line with a then standing policy position that the NIH would not question the reasonableness of company pricing of NIH funded inventions. It is our understanding that HHS is now willing to consider the merits of a march-in request, when

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6 Petition for Xtandi March-In Rights filed by KEI and UACT, January 14, 2016, available at https://www.keionline.org/wp-content/uploads/Xtandi-March-In-Request-Letter-14Jan2016.pdf.

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Now members of Congress have again entered the arena.

the basis is that the price is demonstrably unreasonable.[8]

To this end, the Petition noted that the cost of Xtandi in the US is about $156,000 per year.

Other parties including Universities Allied for Essential Medicine (UAEM)[9] have since asked to join the Xtandi march-in petition.

In a February 2022 statement, the manufacturer of Xtandi, Astellas responded to the November 2021 march-in petition:

Astellas has invested years and more than $1.4 billion to research and develop XTANDI and successfully bring this innovative cancer treatment to market for patients with advanced prostate cancer. XTANDI is priced in line with other oral therapies for advanced prostate cancer available in the U.S. today and is widely available for patients across the health insurance marketplace. Based on an analysis of third-party claims data from January to November of 2021, 71% of US patients paid less than $100 in out-of-pocket costs for their XTANDI prescription regardless of insurance type.[10]

"XTANDI is a prime example of how collaboration between early-stage public research and private development can benefit American consumers, as the Bayh-Dole Act envisioned."[11]

Now members of Congress have again entered the arena. In February 2022, several Members of the House of Representative lead by Representative Peter DeFazio (D - Oregon) and Representative Lloyd Doggett (D - Texas) sent a letter to HHS Secretary Becerra urging him "to move forward with the November 2021 petition to use either march-in or government use rights to remedy the unjustified pricing discrimination against United States residents for Xtandi, a drug to treat prostate cancer that was invented using grant funding from the U.S. Army and the National Institutes of Health".[12] Soon thereafter, Senators Elizabeth Warren (D - Massachusetts) and Angus King (I - Maine) sent a letter to Secretary Becerra advising HHS to "hold a public hearing on the enzalutamide petition to allow petitioners and patent-holders to present arguments and accompanying evidence on this case, and then move forward to exercise the government's march-in rights without delay."[13]

The discourse has become increasingly pointed. In late February 2022, after Astellas's public statement, the Xtandi march-in petitioners wrote to HHS Secretary Becerra alleging that the NIH's review process has not adequately included the petitioners or the public. On the same day, UAEM wrote to HHS Secretary Becerra and Acting Director of the NIH requesting the formal recusal of Dr. Mark Rohrbaugh, the NIH Special Advisor for Technology Transfer, from "any decision-making role" relating to the Xtandi march-in petition. The UAEM letter argued that Dr. Rohrbaugh "is not capable of giving our petition impartial review, nor can he faithfully apply the law as it is written, as opposed to how he subjectively believes it should be."[14] With this letter, UAEM provided emails that allegedly "demonstrate that he holds a bias against march-in rights to address unreasonable pricing". The UAEM letter closed by expressing concern that Dr. Rohrbaugh "has directed NIH officials involved in the 2022 petition to stonewall petitioners" and "requesting a teleconference with someone other than Dr. Rohrbaugh to address these concerns."

The UAEM letter no doubt reflected the petitioners' frustration as in early January 2022, the NIH informed the petitioners that it would take about a month to review the Xtandi petition. On March 17, 2022, the Bayh-Dole Coalition sent a letter to Sec. Becerra urging the HHS to reject the November 2021 Xtandi March-In Rights Petition.[15] In early April 2022, however, having not heard further, the Xtandi petitioners asked for an update, and on April 19, 2022, the NIH responded, explaining that the NIH was carefully reviewing the petition, and "will provide a complete response once the review has been completed and a determination is reached."[16]

As all await the NIH's decision, the outcome will be significant regardless. If the NIH again rejects the November 2021 petition to exercise march-in rights over Xtandi, then it will signal the strength of the NIH's conviction that march-in rights are narrow rights, and therefore, are not intended to address drug pricing concerns *per se*. But, if the NIH grants the November 2021 Xtandi petition, then it will signal a seismic and unprecedented shift in the interpretation of march-in rights, with far-reaching consequences for drug-makers.

As all await the NIH's decision, the outcome will be significant regardless.

Contact

Polsinelli
100 S. Fourth Street, Suite 1000
St. Louis, MO 63102, US
Tel: +1314.889.8000
www.polsinelli.com/

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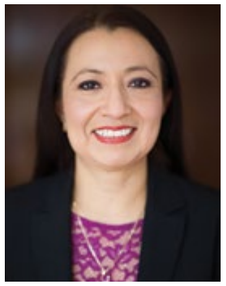
Main applications of CRISPR in life sciences and patent protection of this technology

Janett Lumbreras, Senior Associate at Uhthoff, Gomez Vega & Uhthoff S.C, explains the functions and benefits of CRISPR technology and how it can be protected in Mexico.

CRISPR technology has revolutionized biological research in the last decade and as a result, many academic institutions and companies have patented CRISPR systems and applications in healthcare, agriculture, gene therapy, cosmetic surgery, and many more fields. The technique has enabled the process of genome editing to be very precise, rapid, cost-effective and highly efficient, in contrast with the downfalls that the previously debuted zinc finger nucleases (ZFN) and transcription activator-like effector nucleases (TALEN) technologies showed. However, despite its great potential, challenges including off-target activity, method of delivery, ethical, and regulatory issues still remain unresolved for the CRISPR-Cas systems.

CRISPR-Cas9 is a gene-editing method that can be used in modifying the genome of living organisms, achieving precision changes in a gene, and allowing existing genes to be removed and/or new ones added. CRISPR denotes a system of bacterial immunity found within the genome of unicellular organisms. CRISPR sequences are derived from DNA fragments of bacteria that have previously infected these organisms. They act as an adaptive immune system because they are used to detect and destroy DNA from similar bacteria during new infections.



Janett Lumbreras

Applications of CRISPR in Life Sciences

The first trial of a CRISPR cell therapy was performed in 2019, treating patients with sickle cell disease. The treatment restored fetal hemoglobin, eliminating the need for a functional copy of adult hemoglobin.

Oncology

One of the primary purposes of CRISPR-Cas9 screening in oncology is to identify genotype-specific vulnerabilities. Targeted deletion of these genes can decrease the viability of cancer cells, providing a strategy to discover potential therapeutic targets, while another application is identifying genes that work synergistically with a drug or develop resistance to the drug. Combining CRISPR screening with drug perturbation can provide an understanding of the mechanism of cancer response to drug treatment. CRISPR-Cas9 gene deletion screening in lung cancer cells revealed that KEAP1 deletion in the presence of multiple targeted RTK/Ras/MAPK pathway inhibitors changes cell metabolism, allowing cells to proliferate without MAPK signaling. Thus, loss-of-function screening can help evaluate the efficacy of related drugs in clinical trials and guide treatment selection.

Diagnostics

During the COVID 19 pandemic, CRISPR was used as both a potential therapeutics tool and as a diagnostic tool for the coronavirus. The SHERLOCK™ CRISPR SARS-CoV-2 test kit was granted Emergency Use Authorization from federal authorities to be used in laboratory settings.

Similar diagnostics utilizing the search function of CRISPR-Cas9 have also been engineered to identify other diseases, both infectious and genetic. Early in 2021, Dr. Kiana Aran of Cardea Bio published a study which combined three different Nobel Prize-winning technologies - graphene, transistors, and CRISPR - into a tiny chip that can detect pathogenic single nucleotide polymorphisms (SNPs). Since 50% of disease-causing mutations in humans are SNPs, this is a significant breakthrough in medical diagnostics.

CRISPR animal models

CRISPR-based genome engineering technology has facilitated the rapid generation of alternative *in vivo* and *in vitro* disease models. The new alternatives include the following:

(i) Genome editing in single-cell embryos via direct injection of sgRNAs and Cas9 mRNA. This approach has been used successfully to generate mouse, rat and monkey models, thus revealing the full potential of the CRISPR-Cas9 system for efficient and quick creation of genetically modified animals in which one or several genes have been simultaneously altered.

(ii) *In vivo* gene editing, which involves direct delivery of the CRISPR-Cas9 system to specific cells in their native tissues, thus bypassing the need for germline-modified mutant strains. This alternative can be applied to existing disease models and transgenic strains and has promising applicability in gene therapy strategies.

CRISPR can be used to generate 'humanization knock-ins' in animals like mice - deleting a particular gene or region of DNA in the animal and replacing it with the human version. This level of accuracy is key to understanding and treating human disease. For example, gene-edited animal models of Duchenne Muscular Dystrophy have recently led to significant breakthroughs in treating this disease, including the development of a potential gene therapy, which has been experimentally demonstrated in dogs. It has also been used to create large animal models of neurodegenerative disorders which may lead to clinical trials in the near future.

CRISPR-based disease models have been generated for cancer, neurological diseases and other Mendelian or complex genetic human diseases to investigate the molecular mechanisms underlying pathogenesis. The models are also excellent platforms for testing gene therapy or for high-throughput screening of new drugs.

“However, despite its great potential, challenges including off-target activity, method of delivery, ethical, and regulatory issues still remain unresolved for the CRISPR-Cas systems.”

Stem Cells

CRISPR editing has been a game-changer for stem cell research, since harvesting stem cells from embryos is highly controversial. The advent of induced pluripotent stem cells (iPSCs) was a major breakthrough, because they are adult cells (like skin or blood cells) that have been reprogrammed to become pluripotent.

While human iPSCs avoid the ethical concerns of embryonic stem cells, they remain challenging to work with - not only is it difficult to reprogram and grow iPSCs, but they are also quite resistant to genetic manipulation. CRISPR has not only made reprogramming iPSCs easier, but has also delivered much more efficient results than previous gene editing technologies which were originally used to engineer iPSCs.

Primary cells

In recent years, scientists have provided solutions to increase CRISPR editing efficiency in primary cells, including synchronizing the cell cycle, using chemically modified sgRNAs, creating ribonucleoprotein (RNP) complexes for delivery, and optimizing delivery methods based on the specific cell type. These advances have led to many successful cell therapies, including T cell immunotherapies.

Others

CRISPR has also been applied in live-cell labelling of chromosomal loci, thus facilitating visualization of chromosomal dynamics and increasing our understanding of many fundamental intra-nuclear processes.

Delivery of the programmable nuclease is a key problem in genome engineering. The choice of vehicle for the CRISPR system depends on the purpose of the experiment and can vary from viral to non-viral methods. Vehicles include DNA, mRNA and even ribonucleoprotein complexes (RNP).

Résumé

Janett Lumbreras, Senior Assoicate

Janett has a Pharmaceutical Chemistry-Biology Degree, Diplomat in Access to Worldwide Scientific and Technological Information; and Industrial and Intellectual Property Law from UNAM. She has been Senior Associate at Uhthoff in the Patent Department. She is an active member of AMPPI, AIPLA, CNQFBM.

Viral vectors are promising vehicles for delivery of CRISPR components for two main reasons:

(i) their defined tropism can be re-targeted through almost any tissue or cell type; and

(ii) they can be administered locally or systemically depending on individual requirements.

Patentability of CRISPR

According to the WIPO website, China is the country that has filed more patent applications related to CRISPR followed by USA and Europe respectively, as shown in the table below:

Countries	No. applications
China	2,709
PCT	1,391
United States of America	1,355
European Patent Office	716
Australia	390
Canada	380
Republic of Korea	302
Japan	151
India	136
Singapore	135

"During the COVID 19 pandemic, CRISPR was used as both a potential therapeutics tool and as a diagnostic tool for the coronavirus."

In Mexico, inventions in all fields of technology that are new, resulting of an inventive activity, and susceptible of industrial application shall be patentable, in the terms of the Mexican Federal Law for the Protection of Industrial Property (MFLPIP).

Article 46 of the MFLPIP state that an invention is considered any human creation that allows the transformation of matter or energy that exists in nature, for its use by human and to satisfy its specific needs.

According to article 46 of the MFLPIP the following shall not be considered as inventions:

I.- Discoveries, scientific theories, or their principles;

II.- ...;

III.- ...;

IV.- ...;

V.- ...;

VI.- The ways of presenting information;

VII.- The biological and genetic material, as it is found in nature, and

VIII.- ...

It should also be considered that the following subject-matter shall not be patentable under the provisions of the MFLPIP:

I.- Inventions whose commercial exploitation is contrary to public order or contravene any legal provision, including those whose exploitation must be prevented to protect the health or life of people or animals or plants, or to avoid serious damage to the environment. In particular:

a) The procedures for cloning humans and their products;

b) Procedures for modifying the germline genetic identity of the humans and its products when these imply the possibility of developing a human;

c) The uses of human embryos for industrial or commercial purposes, or

d) The procedures of modification of the genetic identity of the animals, that suppose for these suffering without substantial medical or veterinary utility for humans or the animal, and the resulting animals of said procedures;

II.- Plant varieties and animal breeds, except in the case of microorganisms;

III.- Essentially biological procedures for obtaining plants or animals and products resulting from these procedures.

"CRISPR editing has been a game-changer for stem cell research, since harvesting stem cells from embryos is highly controversial."

The foregoing shall not affect the patentability of inventions whose object is a microbiological procedure or any other technical procedure or a product obtained by such procedures;

IV.- The methods of surgical or therapeutic treatment of the human or animal body and the methods of diagnosis applied to these, and

V.- The human body in the different stages of its constitution and development, as well as the simple discovery of one of its elements, including the total or partial sequence of a gene.

Biological material isolated from its natural environment and obtained through a technical procedure may be subject to a patentable invention, even if it already exists previously in nature.

Therefore, any patent application that falls within any of the above provisions will not be patented in Mexico and it will be necessary to adapt the scope of protection of such applications according to the requirements of the Mexican Legislation.

Several patent applications have been filed in Mexico associated with CRISPR technology and

some of them have been granted, examples of such patents are listed herein below:

Mexican Patent No.	Title
389793	SUPPLY, MODIFICATION AND OPTIMIZATION OF SYSTEMS, METHODS AND COMPOSITIONS FOR THE MANIPULATION OF SEQUENCES AND THERAPEUTIC APPLICATIONS
388092	IMPROVED METHODS FOR MODIFICATION OF TARGET NUCLEIC ACIDS
380562	MODIFICATIONS OF SYSTEMS, METHODS AND COMPOSITIONS OPTIMIZED GUIDE FOR THE MANIPULATION OF SEQUENCES
379552	SUPPLY AND USE OF CRISPR-CAS COMPOSITIONS, VECTORS AND SYSTEMS FOR TARGETED MODIFICATION AND LIVER THERAPY
375420	MULTIPLEXED GENETIC ENGINEERING ENABLED BY CRISPR
374529	SUPPLY, USE AND THERAPEUTIC APPLICATIONS OF CRISPR-CAS SYSTEMS AND COMPOSITIONS FOR GENOME EDITING

Conclusions

CRISPR-Cas9 has revolutionized the field of genome engineering. However, as every powerful tool during the process of development, several potential risks emerge that raise moral concerns, and irresponsible or illegal experimentation with the CRISPR-Cas systems need to be restricted by laws and regulations and supervised by relevant international organizations. A new organization, Association for Responsible Research and Innovation in Genome Editing (ARRIGE), was established by a group of European scientists with a mission of valuing and making policy for the ethical use of genome editing.

Under Mexican Patent Law, the CRISPR technology is susceptible to be patented. However, many people question the ethical and moral implications of the patented CRISPR technology. Therefore, it is uncertain whether these patents should be prevented instead of promoting further research and innovation.

> **Several patent applications have been filed in Mexico associated with CRISPR technology and some of them have been granted.**

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Contact

Uhthoff, Gomez Vega & Uhthoff S.C
Hamburgo 260 col. Juárez 06600
Mexico City
Tel: +52 (55) 55 33 50 60 ext. 1141
jlumbreras@uhthoff.com.mx
www.uhthoff.com.mx

Current controversy around the waiver of intellectual property rights for COVID-19 Vaccines and implications for life sciences companies

Roger Kuan, Jason Novak and Eric Ong examine the threat that the TRIPS Agreement poses to life sciences companies when it comes to protecting their COVID-19 related inventions.

In May 2021, the United States government announced it would support the temporary waiver of intellectual property protections for COVID-19 vaccines under the Trade Related Aspects of Intellectual Property Rights ("TRIPS") Agreement. This effort was well-received by members of the World Trade Organization ("WTO"), including many developing countries, as a step in the right direction to address massive shortages and inequalities in COVID-19 related supplies and distributions.

However, intellectual property rights are just part of a bigger picture of many considerations to deliver practical improvements in global vaccine manufacturing capacity. Merely waiving TRIPS obligations would do little to remedy vaccine production shortages. Rather, it is the time and technical know-how that are the critical drivers for scaling up manufacturing capacity to alleviate the rapid transmission of SARS-CoV-2. These technologies and processes are generally not published in patents, but rather kept as trade secrets. Waiving TRIPS would fail to speed up vaccine production as manufacturers would still not receive the essential trade secrets needed to successfully build and operate the manufacturing facilities necessary to produce safe and effective vaccines. Furthermore, waiving TRIPS would reduce the current level of global vaccine distribution by interfering with access to limited supplies of raw materials and other essential inputs.

While some may believe that COVID-19 and the associated TRIPS waiver is a less relevant discussion now than in 2021, it would be incorrect to conclude as such. Health experts are noting that while it may seem as if "the worst is behind us", the reality is that the virus is still mutating and that the fall of 2022 may be bring more infection variants combined with waning immunity.[1] Moreover, just this past March, a new draft decision text was released, containing some hallmarks of the initial proposed waiver of May 2021, generating a similar negative reaction from the pharma industry.[2]

Therefore, as discussed below, companies possessing patent rights in COVID-19 innovations should be mindful of the circumstances under which a TRIPS waiver might interfere with patent rights to private commercial developments, the consequences of such interference, and the defensive and offensive strategies companies may take to avoid such interference.

Understanding the TRIPS Waiver

In October of 2020, India and South Africa first proposed a waiver of WTO's TRIPS Agreement that would permit countries to suspend intellectual property protections for COVID-19 related vaccines and therapeutics for the duration of the pandemic.[3] The stated goal was to increase access to affordable medical products for the prevention, containment, or treatment of COVID-19, and potentially permit developing countries to manufacture and distribute vaccines independently.[4] Since the announcement from the U.S. government in May, the TRIPS waiver has gained traction among many developing member states, and currently has at least 63 co-sponsors and is supported by more than 100 of WTO's 164 members.[5] The WTO, however, operates by

1 See Anjalee Khemlani, *COVID-19: 'We might not be in a great spot in the fall,' says Moderna CEO*, Yahoo Finance (May 5, 2022), available at https://finance.yahoo.com/news/we-might-not-be-in-a-great-spot-in-the-fall-moderna-ceo-190810232.html.

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5 *Id.*

Résumés

Roger Kuan
Roger Kuan is the US head of the digital health and precision medicine practice at Norton Rose Fulbright. He counsels companies that are uniquely positioned in the convergence of the life/medical sciences and technology industries on how to successfully navigate the complexities of the intellectual property (IP), data rights and regulatory challenges they encounter.

Jason Novak
Jason Novak is a partner in the Digital health and precision medicine practice at Norton Rose Fulbright. His practice focuses on advising entities, both large and small, on the various legal issues that can arise with emerging technologies in the healthcare, food, and life sciences industries, with a particular and targeted focus on "convergence" technologies (e.g., digital health, personalized/precision medicine, alternative protein) that operate at the intersection of multiple industries.

Eric Ong
Eric Ong is a third-year law student at the University of California, Hastings College of the Law. He is a Chancellor's Scholar, an Innovation Law Clinic Scholar, and a Senior Development Editor on the *Hastings Law Journal*. Eric is interested in patent prosecution in the high technology and life sciences industries. Prior to law school, Eric worked as a biochemist at Regeneron Pharmaceuticals where he researched and developed therapeutics for serious diseases. Originally from Taipei, Taiwan, Eric received his B.S. and M.S.E. in Chemical and Biomolecular Engineering from the Johns Hopkins University.

Roger Kuan

Jason Novak

Eric Ong

consensus.[6] If an agreement cannot be reached, a decision to grant the exceptional waiver would need to be adopted by three-quarters of members.[7]

The co-sponsoring countries of the TRIPS waiver have since issued a revised proposal to advance text-based negotiations to the WTO TRIPS Council.[8] The revised waiver covered a range of COVID-19-related "health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture."[9] Yet, the U.S. has called for negotiations specifically around vaccines only.[10] The European Union has submitted its own General Council Declaration (Draft Declaration) to the TRIPS Council to reiterate the use of compulsory licensing and other flexibilities already provided within the TRIPS Agreement's framework.[11] China and Russia, looking to expand their vaccine diplomacy efforts, have announced they would support talks on a waiver at the WTO.[12]

> **The U.S. has called for negotiations specifically around vaccines only.**

As expected, vaccine manufacturers and biotechnology companies have vocally opposed the waiver, arguing that an outright TRIPS waiver would eliminate the incentive for future pharmaceutical innovation, and companies will be reluctant to invest in new technology if they cannot reap full financial benefit from their successes. Pharmaceutical Research and Manufacturers of America ("PhRMA"), a trade group representing companies in the pharmaceutical industry in the United States, and others have announced an alternative approach to the TRIPS waiver.[13] Instead of waiving intellectual property protections, PhRMA is pushing for increased dose sharing through COVAX, optimizing production of vaccines and raw materials, eliminating trade and regulatory barriers, supporting country readiness to deploy vaccination programs, and prioritizing future development of new COVID-19 vaccines.[14]

Given the current situation as it relates to vaccine access and production, particularly in developing countries, WTO member states will need to engage in a series of multilateral dialogues to arrive at any concrete and practical agreement on the TRIPS waiver. Some critics argue that the waiver will not scale up vaccine production because the manufacturing process is overly complex and difficult to develop without extensive support from existing manufacturers under technology transfer agreements.[15] In other words, these critics argue that access to patents may not limit vaccine production, but it is the time and knowledge involved in ramping up manufacturing capacity. Therefore, trade secrets and technology transfer must be critical drivers for advancing vaccine production.

How the TRIPS Waiver Relates to Trade Secrets and Technology Transfer

The TRIPS Agreement only creates obligations for governments to pass laws supporting intellectual property rights, including patents, copyrights, trademarks, and "undisclosed information procedures."[16] The private ownership of these rights is unaffected. Unlike patents, copyrights, and trademarks, trade secrets (or "undisclosed information procedures" as called in TRIPS) do not depend on a government grant but instead only require a robust, reliable legal system that enforces confidentiality.[17] The TRIPS waiver does not suspend national trade secret protection laws nor does it force technology transfer or the transfer of specialized human capital between companies. As a result, without transfer of essential trade secrets, waiving TRIPS would not speed up vaccine production even if there were excess manufacturing capacity available.

Trade secrets are especially critical for mRNA vaccine technologies. These biologics, as compared to more traditional chemical-based small molecules, are complex and require years of experimentation to find optimal cell growth medium, times, temperature, formulation, and other factors. The know-how to manufacture mRNA vaccines at scale, safely and effectively, is owned by few companies like Pfizer/BioNTech and Moderna.[18] These technologies and processes are kept as trade secrets and are not published in patents.

To secure trade secrets and technology transfer, governments would have to negotiate licensing agreements with companies for not only their patents, but also for teams of specialists to travel to and set up safe vaccine production facilities.[19] The TRIPS Agreement does include a compulsory licensing process that allows the manufacturer through its national government to grant a compulsory license, provided the manufacturer has first sought a voluntary licensing agreement.[20] Each compulsory license is related to a specific product, and TRIPS does not have a governing body that regulates this process. Issues related to production capacity, distribution, and production of raw materials and equipment used to manufacture package and transport vaccines are all bottlenecks that exist beyond a TRIPS waiver.[21]

> **As it stands under the current TRIPS waiver proposal, trade secret protections remain unaffected, allowing vaccine manufactures to continue protecting their technical know-how from competitors.**

Considerations and Advice to Life Sciences Companies

With the uncertainty regarding the TRIPS waiver and compulsory licensing, life sciences companies should be wary of governmental intervention in the private research, development, and distribution of any patented COVID-19 product. Patent holders should mitigate and minimize trade secrets and technology transfer misappropriations as early and as much as possible.

As it stands under the current TRIPS waiver proposal, trade secret protections remain unaffected, allowing vaccine manufactures to continue protecting their technical know-how from competitors. If the waiver does not expand in scope, companies can work on reinforcing their trade secret protection plans and expanding their own manufacturing capacity to address any emergency that may arise.

However, if the pandemic worsens with a surge in COVID-19 cases, there may be mounting international pressure to force life sciences companies to take steps beyond the TRIPS waiver. Governments could implement drastic measures to force the transfer of human capital and technical know-how by forcing manufacturing scientists, process engineering, quality assurance professionals to travel to foreign manufacturing sites to disclose their knowledge and trade secrets to build and implement safe vaccine production lines. Under forced technology transfer, life sciences companies risk losing their intellectual property and trade secret rights indefinitely once critical knowledge is disclosed.

As such, patent holders must proactively consider defensive and offensive strategies in which each can avoid interference or minimize the risks of having any expected economic incentives forcibly adjusted.

6 See Article IX of the WTO Agreement, available at *https://www.wto.org/english/res_e/publications_e/ai17_e/wto_agree_art9_jur.pdf.*
7 *Id.*
8 See WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19 REVISED DECISION TEXT (May 25, 2021), available at *https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf.*
9 *Id.*
10 *See Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver*, USTR.GOV (May 5, 2021), *available at https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador- katherine-tai-covid-19-trips-waiver.*
11 See DRAFT GENERAL COUNCIL DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH IN THE CIRCUMSTANCES OF A PANDEMIC (Jun. 18, 2021), *available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W681.pdf.*
12 See John Zarocostas, *What next for a COVID-19 intellectual property waiver?*, THE LANCET (May 22, 2021), *available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8137306/.*
13 *See Five Steps to Urgently Advance COVID-19 Vaccine Equity,* PhRMA (May 19, 2021), *available at https://www.phrma.org/en/Press-Release/Five-Steps-to-Urgently-Advance-COVID-19-Vaccine-Equity.*
14 *Id.*
15 *See Anthony So, WTO TRIPS Waiver for COVID-19 Vaccines,* Johns Hopkins Bloomberg School of Public Health (May 10, 2021), *available at https://www.jhsph.edu/covid-19/articles/wto-trips-waiver-for-covid-19-vaccines.html.*
16 *See* Article 39.2 of the TRIPS Agreement, *available at https://www.wto.org/english/docs_e/legal_e/27-trips_04d_e.htm.*
17 *See* James Pooley, *The Big Secret Behind the Proposed TRIPS Waiver,* IP Watchdog (May 25, 2021), *available at https://www.ipwatchdog.com/2021/05/25/big-secret-behind-proposed-trips-waiver/id=133905/.*
18 *Id.*
19 *Id.*
20 *See* Article 31 of the TRIPS Agreement *available at https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.*
21 *See* John Zarocostas, *What next for a COVID-19 intellectual property waiver?,* THE LANCET (May 22, 2021), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8137306/

Under a defensive and protectionist approach, patent holders should develop robust trade secret protection plans to ensure critical technologies and innovations are well protected. They should frame their protectionist plan to encompass virtually any information that is valuable. This approach allows for intellectual property to remain undisclosed. Information protected by trade secrets is often valuable because it is unknown and not readily ascertainable. Trade secret law provides indefinite protection, as long as the trade secret stays a secret. It also prevents the disclosure or use of a trade secret by one to whom the secret was disclosed. In return, enforceable secrecy leads to more dissemination of technology, not less.

Patent holders should also develop strong internal trade secret programs through required training and strengthened security measures. Companies should have multi-layered checkpoints to ensure employees, particularly exiting employees, are not improperly removing or downloading documents that are critical to their trade secrets and patent portfolios. Furthermore, patent holders could protect their technologies by ensuring no one person or group understands the entire workflow in manufacturing and scale-up production. This will prevent any one person or group to have the independent ability to reconstruct the workflow. Even with the suspension of intellectual property protection, taking defensive steps would ensure patent holders would not have to worry about competitors being able to produce vaccines with critical know-how.

In addition, under an offensive approach, patent holders should proactively secure profitable partnerships and licensing agreements with other manufactures to expand their patent applications. Voluntary technology transfer through licensing would enable manufacturers and plants around the world to scale up quickly and effectively as needed. This tactic would generate additional revenue for the patent holders while simultaneously ensuring their intellectual property, including undisclosed information procedures, is secured. In the interest of the manufacturers, patent holders could agree to lower licensing royalty rates to encourage cooperation and market accessibility. Most importantly, patent holders would not be forced to enter into compulsory licensing agreements because governments would have no incentive to do so in a robust, and scalable production assembly. Companies should enter favorable negotiations on their terms instead of waiting for a health crisis during which harsh public policy could force patent holders to enter into unfavorable financial situations.

Regarding PhRMA's alternative approach, expanding dose sharing to low- and lower-middle-income countries would force more equitable vaccine distribution. Similarly, eliminating trade barriers would allow easier import and export of key manufacturing materials and vaccines, along with the prioritized movement of the skilled workforce needed for COVID-19 vaccine manufacturing. However, setting up and optimizing production is a time-intensive and arduous process that would likely take a new vaccine manufacturer years to come online and produce vaccines that are safe for the public to use.

> **Patent holders must proactively consider defensive and offensive strategies in which each can avoid interference or minimize the risks of having any expected economic incentives forcibly adjusted.**

Governments and life sciences companies must recognize the uncertainty and repercussions that would remain once intellectual property protections are removed. Expanding vaccine production to unlicensed manufacturers could worsen the already strained demand for limited raw materials and challenging supply chain issues. Companies risk losing their proprietary technologies and competitively sensitive trade secret information indefinitely without reaping the financial rewards for their efforts. Even if the TRIPS waiver is limited to just three years as it currently stands, the waiver does set a precedent that may incentivize companies to keep more of their innovation under wraps as trade secrets instead of trying to obtain patent protection for them. This in turn may be detrimental to the pace of future advancements in COVID-19 treatments. Moreover, if the TRIPS waiver was extended beyond three years, it could incentivize governments, companies, or private investors to commit the capital necessary to start new follow-on biologics manufacturing plants to complete with branded biologics manufacturers. For small molecule, chemical-based therapeutics that do not involve much technical know-how or specialized human capital to manufacture, an TRIPS (extended or not) waiver will likely result in generics competition.

The world needs to recognize the importance of a strong, predictable, and globally harmonized intellectual property system. Strong intellectual property protections provide incentives for companies to create new and groundbreaking technologies. These incentives were critical in driving the private sector to develop COVID-19 vaccines and therapeutics, in the first place, in record time. Life sciences companies should actively consider defensive and offensive strategies to secure their proprietary products and technologies. Only then will the world be best prepared for the next public health emergency.

Contact

Norton Rose Fulbright US LLP
555 California Street
Suite 3300
San Francisco,
California 94104
United States
Tel: +1 628 231 6800
https://www.nortonrosefulbright.com/en-us/locations/san-francisco

360° degree intellectual property protection in the healthcare industry

Ricardo Costa Macedo, Head of the Life Sciences and Intellectual Property groups at Caiado Guerreiro, clarifies the available intellectual property protection in the healthcare industry including trademarks, patents, domain names, and trade secrets.

It is known that there is an increased demand for health services across the world. Global population growth, aging population and an increased pace of medical advances are some of the factors contributing to the higher demand for health care services. According to Eurostat data, the current healthcare expenditure relative to Gross Domestic Product in 2019 in the European Union was of 9.92%, being that among the EU Member States, Germany (11.7 %) and France (11.1 %) had the highest healthcare expenditure relative to Gross Domestic Product in 2019, Portugal having a 9.53% healthcare expenditure relative to Gross Domestic Product in said year.

A relatively consensual definition of health care industry (also called the medical industry or health economy) is an aggregation and integration of sectors within the economic system that provides goods and services to treat patients with curative, preventive, rehabilitative, and palliative care.

According to the United Nations International Standard Industrial Classification (ISIC), the healthcare industry generally consists of hospital activities, medical and dental practice activities and "Other human health activities", the latter involving activities of, or under the supervision of, nurses, midwives, physiotherapists, scientific or diagnostic laboratories, pathology clinics, residential health facilities, or other allied health professions, e.g., in the field of optometry, hydrotherapy, medical massage, yoga therapy, music therapy, occupational therapy, speech therapy, chiropody, homeopathy, chiropractic, acupuncture, etc.

Ricardo Costa Macedo

Trends in the Health Care Industry for 2022

In the wake of the COVID-19 pandemic, it is already clear that significant changes were

Résumé

Ricardo Costa Macedo, Lawyer and Partner at Caiado Guerreiro, head of the Life Sciences and Intellectual Property groups.

Mr. Macedo´s practice covers a wide range of contentious and non-contentious patent, trademark and other IP-related rights, such as trade secrets and unfair competition, in particular in the pharmaceutical, home care, food and insurance sectors. Moreover, he has vast knowledge in regulatory matters in these sectors.

Mr. Macedo Graduated in 1998, in the Faculty of Law of the Catholic University of Lisbon. He undertook postgraduate studies in information society law at the Faculty of Law of the University of Lisbon in 2000 and in commercial law at the College of Law, London in 2003.

implemented as a result of said pandemic. The health care industry changed too.

While many more changes will come in the future for the health care industry, some are more significant and apparent than others.

Amongst the more significant and apparent changes in the health care industry one can enlist various changes.

The adoption of telemedicine is certainly one of them. Just a few decades ago a patient video-calling his/her physician was not possible, whereas nowadays many doctors are happy to interact with their patients from a distance via a video or phone call.

Integrated medical technologies are also a trend of today: electronic health records, medical internet of things, artificial intelligence, remote monitoring, all congregate to transform in many ways the way in which health care is provided.

Another consensual change that is appearing on the horizon for health care service is more personalization in health care. This can be tied-up with another trend which is the increase in home care services vs. hospital care services.

All of these trends can and should be considered in the context of protecting intellectual property assets.

Trademark protection

Trademarks in the health care industry are an important mechanism in the strategy to promote not only innovation, but also to build the sense of identification for consumers with companies.

> **A trademark is a sign used in commerce to distinguish and identify a company's products and services from those of other companies.**

If a company has decided to act in the health care industry, it should make sure that its company name and any product or service are trademark protected.

Although trademarking is not often on the business agenda of entrepreneurs in this sector, the right selection of a trademark helps to build a strong image.

In fact, a trademark is a sign used in commerce to distinguish and identify a company's products and services from those of other companies. Trademarking helps the consumer to find the desired products, which builds the reputation of the trademark and also encourages its holder to maintain the quality of its products.

After choosing possible names for their services and products, health care providers should consider conducting a prior search to assess possible confusion between their trademark with others to ensure that the desired trademark is not already in use or that the trademark does not have a negative meaning in certain countries.

Prior research also prevents facing a possible infringement or unfair competition claim from other trademark owners or representatives.

In the specific case of medicinal products, there are of course regulatory provisions that should be considered in the context of trademark protection.

Patents

A patent right attributes the exclusive right of exploring the invention in a certain territory to the holder of such right.

A patent right may be transmitted either free of charge or onerously. The transmission of patent rights is perceived as a fundamental characteristic of the patent system.

The right to the attribution of a patent belongs to its inventor or to the inventor's heirs.

Patents are titles of invention, meaning, industrial property rights intended to protect inventions. The patent as granted will be the starting point for the clarification of the scope of protection of the patent.

The protection of the patent allows for the exploitation of the patented invention in a certain territory. This establishes the positive content of the patent right, granting its inventor the right to practice and use the patented invention within a limited territory, in light of the territorial scope of patent rights.

On the other hand, there is also a known negative content of the patent right, meaning it attributes to the patent holder the right to prevent unauthorized third parties from using the patent and profiting from what is thought to be an exclusive right (thus precluding third parties from benefitting from the inherent economic rights).

Provided that the usual requirements of novelty, inventive step and utility are met, patents are traditionally a strong option to be considered for any individual or entity acting in the health care industry who wishes to protect its intellectual property rights.

> **Patents are a strong option to be considered for any individual or entity acting in the health care industry who wishes to protect its intellectual property rights.**

Trade secrets

In a highly competitive and fast-changing reality, the ability to innovate in the creation of products and solutions is key to the success of a company in the health care industry. Trade secrets are often a crucial part of this process, thus giving a competitive advantage to its holders in their market.

Misappropriation can mean the loss of this advantage over competitors because the secret loses its core quality: not being widely known.

If a trade secret of a technical nature is at stake, the loss may result in that a process that was exclusive becomes replicable by others.

If it is a trade secret of a more commercial nature, the company may be exposed in its strategy, resources or contacts.

It should also be noted that business secrets often result from a prior investment, which makes their misappropriation a double loss: because of the loss of future income and because of the past investment that is no longer recoverable.

And what exactly constitutes a trade secret? According to Article 39º (2) of the TRIPS Agreement, a trade secret is information that: (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) has commercial value because it is secret; and (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

There are several measures a health care provider may and should take to protect its trade secrets and these can be factual or legal.

Domain names

In the age of the internet, it is very relevant to have a trademark aligned with a domain name, and that is also the case in the health care industry. As such, domain name availability is an important aspect when selecting a trademark, and so is owning the right domain name and ensuring the exclusive right of using such a domain name.

Conclusion

There is a growing demand for health services across the world, which is also a growingly competitive environment. Individuals and companies acting in this sector have a wide range of intellectual property rights that can and should be used in order to secure their position in the marketplace. An increasing perception of the value of intangible assets alongside already identified trends in the health care industry advise careful consideration of intellectual property protection.

Contact

Caiado Guerreiro,
Sociedade de Advogados, SP, RL
Rua Castilho, 39, 15º
1250-068 Lisbon
Portugal
Tel.: + 351 21 371 70 00
Fax.: 351 21 371 70 01
rmacedo@caiadoguerreiro.com
www.caiadoguerreiro.com

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Via L. Manara 13
20122 **MILANO**
Tel: +39 02 54120878
Email: glp.mi@glp.eu

Viale Europa Unita 171
33100 **UDINE**
Tel: +39 0432 506388
Email: glp@glp.eu

Via di Corticella 181/4
40128 **BOLOGNA**
Tel: +39 051 328365
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