

## **The CRISPR/Cas9 case before the European Patent Office**

On the 17th of January 2020 the European Patent Office made a final decision in a high profile CRISPR/Cas9 case. Although we still have to wait for a written justification to be published, the verdict of the Board of Appeals has already been announced.

It has to be underlined that this case has attracted considerable attention from its early stages and its progress has been followed carefully by professionals, experts and enthusiasts of the subject alike. The spotlight belongs to a technology that is widely recognized as one of the most significant scientific inventions of the 21st century. The possibilities it might offer seem astounding: scientists speculate that it might be applied in medicine to fight HIV virus and Hepatitis C virus, while in agriculture it might permit to genetically improve crops on a scale unseen before; not without a significance is a fact that the employment of this method is expected to be highly lucrative. The potential profits it might produce are clearly a significant factor that stimulates fierce competition among subjects that develop this technology.

In this issue of the WTS Legal Report we would like to present you the state of affairs in the case, highlighting the contentious issues and the arguments made by different parties.

### **What is CRISPR/Cas9**

To begin with, it would be useful to recount some elementary facts concerning the technology at issue. As in case of a majority of great inventions, it did not come out of thin air: it is once again a story of a man watching closely the nature and then trying to mimic it. This particular method of biotechnological engineering is based on an prokaryotic immune system that such organisms as bacteria and archaea have been observed to use; its name CRISPR is short for: *Clustered Regularly Interspaced Short Palindromic Repeats*. Because of their capability to store in their genomes fragments of foreign DNA (obtained

for example during viral infections), bacteria and archaea in case of a subsequent contact can quickly identify and destroy that DNA. That action is performed through the use of nuclease, an enzyme that serves to cleave complementary DNA threads. The same enzyme is utilized in the CRISPR/Cas9 technology: the CRISPR system engages selectively with a separate DNA sequence and at the same time the endonuclease Cas9 is activated to cut through the threads in vicinity of this part of the genome. Therefore a door to carry out precise modifications of the DNA code is opened.

### **Facts in the case**

The history of legal disputes that concern CRISPR/Cas9 dates back to 2012. This was when prof. Jennifer Doudna of the University of California in Berkeley along with prof. Emmanuelle Charpentier were the first to file an application to patent CRISPR/Cas9. Soon afterwards prof. Feng Zhang of the Broad University was granted a patent to use such a technology to modify genomes of eukaryotic cells. Following years witnessed a long-running series of clashes between these two institutions — both before the United States Patent and Trademark Office (USPTO), as well as before courts in jurisdictions of distinct states. Since then, the number of players in the field started to increase rapidly — other institutions, enterprises and scientific teams were patenting their own inventions based on CRISPR/Cas9.

The Broad University was granted a European patent no. P2771468 upon an application filed on December 12, 2013. The EPO, while reviewing it, referred to the previous applications that had been made by the Broad University before the USPTO. The EPO pointed out that despite former applications mentioning prof. Luciano Marraffini of the Rockefeller University in New York among the inventors, his name was absent from the subsequent application. At the same time it was determined that prof. Marraffini had not transferred his entitlement to priority to the Broad University, but to the Rockefeller University with which he had been affiliated.

In October and November of 2015 nine parties raised objections against the patent that the Broad University was granted for CRISPR/Cas9. After reviewing those objections, the Board of Appeals declared on March 26, 2018 that the discrepancies between the lists of persons filing subsequent applications deprived American priority applications of their evidential value. It is therefore impossible to declare on their grounds that the Broad University was allowed to properly claim priority — and since that claim did not produce any legal effects, the invention in question lacked novelty in view of the prior art. Ergo, it failed to meet an essential requirement of patentability.

The Broad University lodged an appeal just two days later (March 28, 2018); the oral part of the proceedings in the case took place from January 13 to January 17, 2020.

At its closure the Board of Appeals has issued its final decision: the Broad University's complaint was overruled and its patent revoked.

### **Legal questions: who is “any person”?**

In a communication issued on November 4, 2019, the Board of Appeals presented the core issue at stake with these words: “A and B are applicants for the priority application. A alone is the applicant of the subsequent application. Is this priority claim valid even without any assignment of priority right from B to A?”.

The key point of reference in this case shall be Article 87 of the Convention on the Grant of European Patents (from now on referred to as: EPC). According to its wording, any person who has duly filed, in or for any State party to the Paris Convention for the Protection of Industrial Property or any Member of the World Trade Organization, an application for a patent, a utility model or a utility certificate, or his successor in title, shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of twelve months from the date of filing of the first application. Followingly, Article 88 stipulates that an applicant desiring to take advantage of the priority of a previous application shall file a declaration of priority and any other document required, in accordance with the Implementing Regulations.

Some controversies arise when it comes to the correct understanding of a term “any person” that is used in Article 87 Section 1 of EPC. The appellants claim that “any person” should be construed as anyone who was among those who filed the priority application. To corroborate this thesis, they invoke Article 4 Section A of Paris Convention for the Protection of Industrial Property of 1883 that contained a similar provision, in which it was stated that any person who has duly filed an application for a patent, or for the registration of a utility model, or of an industrial design, or of a trademark, in one of the countries of the Union, or his successor in title, shall enjoy, for the purpose of filing in the other countries, a right of priority during the periods fixed in the Convention. In the opinion of the appellants, the rules of linguistic interpretation require to distinguish the denotation of the specific expressions applied in both conventions and the set of all parties filing a priority application. They refer to rules established in Vienna Convention on the Law of Treaties, particularly to a directive according primacy to the ordinary meaning of terms that are used in a legal document.

In the communication of November 4, 2019 the Appellate Panel addressed those arguments, stating that an expression “any” is “ambiguous” and that it renders “attempts to elucidate the meaning of these provisions upon a purely linguistic basis difficult and most unlikely to be successful”.

It has to be underscored that by proposing the aforementioned interpretations, the appellants oppose the well-established caselaw of the EPO in this field. For instance, in its decision in the case T 0788/05 of May 8, 2007, the Board of Appeals declared that “the priority right belongs simultaneously and jointly to the two applicants, who thus constitute a legal unity unless one of them decides to transfer his right to the other applicant, who then becomes his successor in title and this before the filing of the later application”. Even in the communication already mentioned the Board of Appeals indicated that in the light of its existing body of rulings, the respondents’ position that all applicants listed in the priority application need to be listed in the subsequent application, shall be expected to merit approval. However, the appellants tried to convince the Board of Appeals that their case differs significantly from cases that were previously reviewed by the EPO: according to them, the crucial question in the past proceedings revolved around the correctness of the transfer of competence, unlike in CRISPR/Cas9 where a problem that had to be solved was who was primarily entitled to the right to priority and who was entitled to transfer it to other subjects.

The Board of Appeals demonstrated in its communication that a decision it had to make in the pending case, came down to choosing between maintaining or altering its fixed practice. It weighed the pros and cons of both solutions (in its opinion, factors speaking for making a decision in line with the current caselaw included, i.a., durability of the current practice, the risk of multiple subsequent applications that might have inundated the EOP otherwise; while the factors that favored breaking with the fixed practice were, to name a few, a search for greater level of compliance with the goals set forth in Paris Convention, i.e. facilitating international patenting, as well as guaranteeing more security to the joint applicants). Nonetheless, it needs to be remarked that by highlighting the aspects that needed to be taken into consideration, the Board of Appeals signaled indirectly that a possibility for a reversal in its caselaw, even if faint, did occur.

### **Legal questions: application of national law**

The appellants put forward a request to construe the term “any person” in the light of appropriate provisions of internal law of given countries — in this case, the USA. In their argumentation they brought into focus a specific moment when the right to priority comes into existence. According to them, this event takes place at the moment of filing of the first application, not subsequent ones. What was supposed to favor their position, was a fact that from this very moment the right can be transferred to another subject — therefore before it is invoked in a following application; and it would be ludicrous to transfer effectively something that does not yet exist.

They argue that Article 87 of EPC, by means of referring to “duly filing” an application in a given country, points expressly to the national law — thus it is the national

law on whose grounds the meeting of procedural requirements and the existence of the right to priority shall be evaluated. It is worth to cite in this place an excerpt from the appeal: “Although Article 87 EPC is in a sense a complete code on priority, this does not mean that the correct interpretation of Article 87 takes place in a vacuum. By itself Article 87 EPC does not provide a complete answer to all questions that may arise”. The appellants claim that the only logical consequence would be to resolve the issue on the grounds of the US law. The rule derived from the American caselaw states that only the inventor-applicants who contributed to the invention can be deemed “any person” in the meaning of Article 87 of EPC, therefore its application allows us to reach an unequivocal conclusion.

The response to the argument regarding the role of national law in claiming priority has been presented in the Board’s of Appeals communication of November 2019. The Board confronts the appellants’ objections with a position that the EPC establishes a complete system for determining the issues lying at the core of the dispute. For this reason, all the references to regulations of internal legal orders, according to the Board members, do not have any rationale and the matter of choosing the proper law to verify the correctness of a particular transfer of priority is utterly irrelevant.

### **Legal questions: setting limits of competences**

Notwithstanding the arguments discussed above, the appellants present some more far-reaching polemic. In their opinion, entitlement to priority shall be recognized by national courts instead of the EPO. They argue that the EPO, as a body that is equipped with a special technical expertise, shall evaluate mainly the scientific dimensions of inventions with regards to the patentability criteria as laid down in conventions. They mention Article 60 Section 3 as a valuable hint in terms of determining the actual scope of the EPO’s competence. According to this provision, in proceedings before the EPO, the applicant shall be deemed to be entitled to exercise the right to a European patent. It is a commonly accepted stance that tasks regarding the assessment of ownership of property rights of a given subject shall fall outside the EPO’s competence.

The appellants acknowledge a decision of the Board of Appeals in the case T 1201/14 wherein the Board asserted that the priority entitlement is an item of property as a substantive property right. In order to ascertain in whom it is vested, it would be necessary to investigate the applicant’s entitlement, which is expressly prohibited on the grounds of Article 60 Section 3. The Board of Appeals, as the appellants noticed, in the justification of that decision defended however the adequacy of “the same applicant” criteria, suggesting that it does not pertain to the matter of ownership but it rather involves a simple verification whether the applicant of the subsequent application is the applicant of the priority application and their rightful successor in title. The appellants challenge this position by

pointing out that in numerous cases it may actually lead to cancelling protection; all that is sufficient for a patent to become invalid are minor procedural lapses in course of a transfer of a right to priority.

The appellants claim that the assessment of priority entitlement carried out by the EPO does not serve any purpose: in this context they refer to Article 88 of EPC and Rules 52 and 53 of the Implementing Regulations that establish detailed regulations that concern claiming of priority (including: a duty to notify the date of filing of a priority application, use of a special form, a possibility of modifying a claim, required documents, translations, etc.). They state that those particular provisions warrant a connection between the priority applicant and the applicant claiming priority. For that reason an investigation conducted by the EPO in that area proves superfluous, and the requirements presented in its caselaw transgress remarkably the EPO's mandate to verify procedural issues. They discuss also the situation of third parties and try to determine what measures are the most effective in terms of providing them with legal certainty. According to them, those parties are best protected when the technical identity of the inventions featured in subsequent applications is ensured. If priority has effectively been claimed, the competitors, when making their own economic decisions, would pay attention mostly to the invention that is an object of a given application, caring less about who exactly has filed it.

### **SUMMARY: THE EPO'S DECISION**

As was stated before, the decision has already been announced: we do know that the Board of Appeals chose to revoke the patent EP 2771468, and as an immediate reason for this ruling it invoked the fact that the technology covered by the patent did not fulfill the novelty requirement. The matter was resolved without a referral to the Enlarged Board (a possibility that has been brought out at some earlier stage of the proceedings). Right now we are waiting for the justification in writing — it would undoubtedly offer a lot of material to reflect upon and discuss at length.

As for the Broad University, it is assumed to perceive the decision of the Board of Appeals as a major disappointment; it is worth to notice however that it does not mean the end of its legal battles before the EOP. The institution has still several pending European patent applications; two of their cases that similarly concern an issue of priority, were referred to the Board of Appeals. Right now it would not be reasonable to rule out with absolute certainty the possibility that one of them would reach the level of the Enlarged Board and in the long run a practice of the EPO in that area might still be altered.