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IN THIS ISSUE

CRISPR: GENE EDITING TECHNOLOGY EPO REVOKES PATENT

The CRISPR – Cas (Clustered Regularly Interspaced Short Palindromic Repeats) system is an immune defence mechanism used by some organisms in nature (such as bacteria) to defend themselves against viruses. These organisms have RNA fragments known as CRISPR that are molecular sentinels used to detect and destroy foreign DNA sequences. Once the foreign DNA has been recognized and engaged, CRISPs guide a so-called Cas (CRISP-associated) endonuclease enzyme that cleaves the invading DNA preventing it from replicating.

For some years now there have been numerous attempts on the part of biotechnicians to use this system as a powerful and accurate tool for genetic modification, also more user friendly and affordable compared to existing technologies. Thanks to the CRISPR/Cas system, genes of many organisms (such as animals and plants) can be permanently modified.

Given the great interest of the scientific community in the CRISPR-Cas system, the recent decision of the European Patent Office's Board of Appeal to uphold the revocation of a European patent granted to the US company Broad Institute Inc. is of prime importance.

European Patent No EP2771468 was filed on 12.12.2013 by the Broad Institute, claiming priority from a series of US patent applications filed by multiple applicants. The European patent was granted on 11 February 2015.

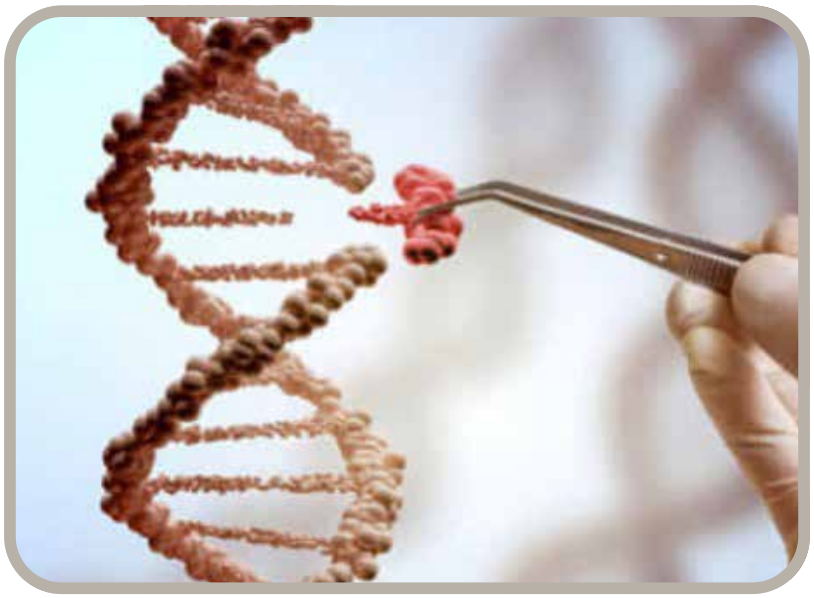
Opposition to the patent was filed in October 2015. Among the various grounds for opposition was the fact that priority rights had not been correctly transferred by all of the US co-applicants and the Broad Institute therefore did not have the right to file the European patent in its name.

The question essentially involves disagreement between the Broad Institute and **New York's Rockefeller University** as to who should be named as inventor. Specifically, the first US filings named the microbiologist **Luciano Marraffini** of Rockefeller University as co-inventor, although his name was missing in the subsequent documents. The absence of Marraffini as inventor would result in loss of the right to claim the *"priority date"* of the first US patents by the Broad Institute Inc.

According to the strict European rules for claiming priority, two minimum requirements must be fulfilled: same invention and same right holder. Where priority is transferred to a third party, the deed of assignment must be dated prior to the filing date of the European patent.

The Broad Institute thus lost priority from the first two US patents, and many of the scientific papers published by the inventors therefore became relevant for the question of novelty, the EPO's Opposition Division deciding to revoke the patent on 26.03.2018 under Art. 138.1(a) of the EPC due to lack of novelty and the inventive step.

The Broad Institute obviously appealed against the decision of the Opposition Division, but the EPO's Board of Appeal upheld the decision on 16.01.2020, again stating that the first and second priorities claimed by the European patent were invalid. The patent was therefore finally revoked.



Chiara Formenton
European Patent Attorney

A BUSINESS THAT KILLS

Of all counterfeit products, fake medicines should be seen as an underestimated phenomenon which nonetheless has very serious consequences, causing hundreds **of thousands of deaths each year.**

We are dealing with falsification of life-saving medicines, such as fake anti-malaria tablets made in China and fake meningococcus vaccines that instead of preventing illness cause meningitis epidemics.

The Lomè Initiative was launched in **Lomé, Togo,** on 17 and 18 January of this year , bringing together the heads of seven African states over two days to sign an agreement aimed at establishing strict common rules and finding more effective ways to combat this form of crime.

The heads of state of Togo, **Congo**, Gambia, **Ghana**, Niger, **Uganda** and **Senegal** signed a binding declaration on combating counterfeit medicines, a type of crime for which many

The extent of the problem can be evaluated from the statistics: in Sub-Saharan Africa in 2015, **122,000 children** under the age of five died due to substandard anti-malaria medicines; in **Angola** in 2012 a container originating in China was seized, loaded with **1.4 million boxes** of false **anti-malaria tablets** containing calcium phosphate, fatty acids and yellow colouring, without any active ingredient whatsoever.

In **Niger**, between 2017 and 2019, **false meningococcus vaccines** originating in **India** caused various **meningitis epidemics** resulting in 358 deaths**.**

The plague of counterfeit medicines has spread to no fewer than 128 countries worldwide, of which 42% in Sub-Saharan Africa, where 30% to 60% of the internal market is made up of fakes.

The phenomenon is no longer a question of illegal trade in the streets and at market stalls: fake drugs are now on sale in pharmacies and supermarkets, where they are bought by unsuspecting consumers.

countries have yet to provide for in their legal codes.

The signatories also put their name to two highly important international agreements: the **Medicrime Convention**, a Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (signed in Moscow in 2011), and the **Palermo Convention**, i.e. the United Nations Convention against Transnational Organized Crime (adopted in the Sicilian capital in 2000).

The World Health Organisation estimates that the fake drugs business is now worth $200 billion each year, or between 10% and 15% of the global pharmaceutical market, its proceeds going towards financing international crime and even terrorist groups.

According to Interpol and the WHO, the main points of origin of false medicines are Asia, China and India, where genuine generic drugs are manufactured by day and fakes by night, all destined for the export market.

Interpol has launched several operations against fake drugs trafficking down through the years, including Operation Pangea, which in 2018 alone led to the seizure of 10 million units, or Operation Heera, involving seizure of 95,800 units in West Africa with a value of 3.8 million dollars.

The International Institute of Research Against Counterfeit Medicines (IRACM) estimates that for every $1,000 invested, criminal organisations can earn up to $500,000.

What is most worrying is that the main factor driving the illegal trade in fakes is the excessive cost of legal medicines produced by the large pharmaceutical organisations, which are completely unaffordable for poor consumers in many countries.

Claudia Strola
Research Manager

AN AI MACHINE
CANNOT BE AN INVENTOR, ACCORDING TO THE EPO

"A machine called DABUS conceived of the present invention.".

This is the opening sentence of two letters by a UK firm of patent attorneys in July last to the European Patent Office in reply to a request to specify the inventor in two filed patent applications.

IN THE MATTER OF
EUROPEAN APPLICATION NUMBER EP18275163.6
FOOD CONTAINER

Designation of Inventorship (EPO Form 1002)

A machine called "DABUS" conceived of the present invention

Ordinary enough applications, like thousands of others examined by the EPO every day, for a food container and "*devices to attract attention*" (or put simply, bright lights).

The request to designate an artificial intelligence system as the inventor is however somewhat less common and raises important questions on the present and future of the entire European patent system.

There is general acknowledgement that the continuous progress being made in the area of design of machines capable of performing typically human functions and reasoning, in a fully autonomous manner, will soon lead to an increase in situations like that featuring Dabus.

The question also raises a more general reflection on whether, departing from a fundamental and universal precept of all intellectual property law, inventions and creations can be attributed to entities other than natural persons (as in the

well-known dispute regarding copyright attribution for the *selfie* taken by the macaque monkey Naruto using the camera of a famous photographer).

At least for now, in the patent area, the EPO's position appears to be written in stone, with no change of direction in sight: the designated inventor in any patent application must be human.

The applicant's attorneys were unsuccessful in their attempts to challenge this position, in particular using the argument that to deny the possibility of designating AI systems as inventors would amount to de facto exclusion from patentability of inventions made by such systems.

On the other hand, the EPO's decision is hardly surprising, adopting as it does the existing rigorous and cautious position

The patent applications designating the machine Dabus as the inventor were rejected by decision of 27 January 2020.

The line reasoning followed by the EPO is based essentially on the combined provisions of Article 81 of the Convention (*The European patent application shall designate the inventor.*) and Rule 19 of the relevant implementing regulation (*The designation shall state the family name, given names and full address of the inventor*).

that has been expressed, inter alia, at a number of EPO-related events, including the Munich Conference of 30 May 2018.

Given this situation, it seems evident that – regardless of the admirable but, as we have seen in the Dabus case, vain attempts by those operating in the sector to bring about change – only legislative reform of the current rules under the Convention, increasingly viewed as outdated, can lay the basis for a future European patent system by adapting it to the patterns and needs of artificial intelligence.

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