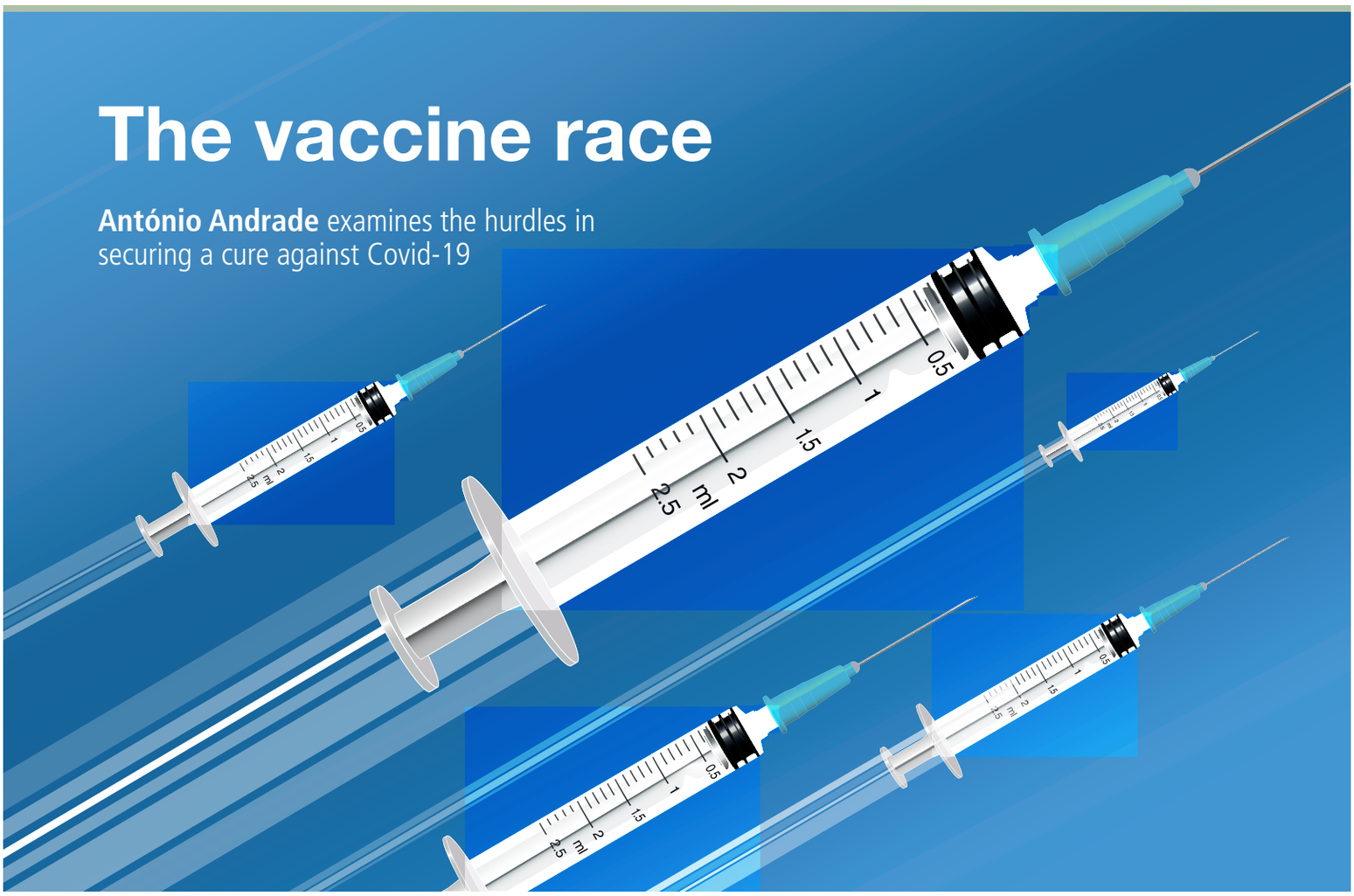
The vaccine race

António Andrade examines the hurdles in securing a cure against Covid-19



Pharmaceutical companies around the world in countries including China, Germany, Japan, the UK and the US are conducting around 20 lines of research and testing for a potential Covid-19 vaccine.

This is a race against time which raises, in the current circumstances, difficulties and constraints in relation to the protection of chemical or biological technology protected by intellectual property rights connecting to any resulting viable vaccine.

The traditional form of patent protection across all industries – complies with legal criteria governed by the legislation of individual countries. In global terms, such legislation is well harmonised in the sense that all patents, which are roughly a technical solution to a technical problem, must satisfy the criteria of novelty, inventiveness and industrial applicability.

Novelty

Novelty is a universal concept. The technical solution contained in the patent must be new, meaning that it cannot have been previously and publicly disclosed anywhere in the world as part of earlier patents, technical documents, technical studies, academics and others.

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Inventive step

The inventive step determines that, on the date of patent application, the technical solution to be patented cannot be obvious to a person skilled in the art and based on the state of the art, ie, in relation to everything that has been published in the technical area concerned. The question is whether the person skilled in the art would find the technical solution as obvious or evident, based on the current state of the art. If the answer is positive it means that the development lacks an inventive step and is not patentable. If the answer is negative the conclusion is the opposite.

Industrial applicability

The third legal requirement for patentability is industrial applicability, which essentially means that manufacture of the technical solution must be scalable to industrial-scale production, and not just at laboratory scale.

The application for the patent can be filed via different territorial protection routes, ie, at national level (country by country), at a regional level, for example through the European Patent Convention and through international patent application via the Patent Cooperation Treaty. In relation to all these routes assessing the application takes time, in particular the examination of the patentability requirements. From a practical standpoint, this means that it would not be possible to receive

the granting of a patent covering a potential Covid-19 vaccine that has novelty, inventive step and industrial applicability in less than one to two years.

It should also be noted that, in pandemic situations such as the one we are experiencing, the law may require mandatory or compulsory licensing by governments, which means that the patent holder is "forced" to grant consent of use and marketing of the patented vaccine to a government.

Although this solution has never been applied to pharmaceutical patents in Portugal (it has in other countries), it can always be theoretically considered in the framework of the intellectual property law in force in Portugal (Industrial Property Code). Nevertheless, we believe there is no need to resort to this extreme measure.

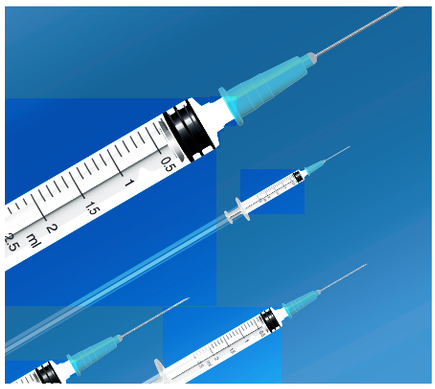
Should it be implemented, the government of a country where a mandatory licence is determined should seriously consider possible economic retaliations from the country where the patent holder is based.

The fact that it can take up to two years for a patent to be granted is not a viable timeframe considering the urgency in defeating the Covid-19 pandemic. There are, however, options which, on the one hand, would compensate the pharmaceutical or biotechnology company for its enormous investment in the development of a Covid-19 vaccine and, on the other hand, would make the vaccine immediately available to the whole population without demanding market exclusivity that the patent assures the company.

A voucher system could be an option. This would consist of an agreement between the government and the pharmaceutical or biotechnology company delivering the technical solution that is sought (ie, a Covid-19 vaccine). The system would provide for the free transfer to the government of this – even patentable – technology, allowing it to be produced and distributed by other companies designated by the state, thus making it readily available to the entire population.

In exchange for this, the government would grant extended protection (from two to five years) – and the respective market exclusivity – for a patent related to any chosen drug in the portfolio of patented drugs of the company that provided the technology used to develop a Covid-19 vaccine.

This system could financially compensate the company for high research and development (R&D) costs incurred to develop the vaccine, once the company gives up patent protection of the vaccine, consequently forfeiting market exclusivity that the patent would provide.



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However, such an exception that determines the extension of the protection of a patent (beyond the normal date of expiry of the patent, which is 20 years from the filing of the patent application), and the respective extension of the market exclusivity period that the patent ensures, may raise complex issues in relation to competition law. In fact, the extension of the expiry date of the patent prevents competing companies from launching generic versions of the patented product onto the market, without the patentee's consent, during the extended period.

An alternative is the reward system, which consists of a government financial reward granted to the company that develops the vaccine first and resigns patent protection. However, "generous" the financial reward may be, it will never cover the R&D costs incurred for the vaccine.

Moreover, the reward system, as a one-off compensation, does not make up for the profit opportunities arising from the patent throughout the 20-year period of its validity.

For these reasons, this system does not really offer an incentive for the pharmaceutical industry.

It remains to be said that intellectual property will in no way impede all research for the desired vaccine; on the contrary, the protection of the respective technical solution under a patent would be fair and logical.

Patent rights remain the best way to compensate the pharmaceutical company for the astronomical cost of the R&D required to develop novel technical solution – which include an inventive step, industrial applicability and scalability – that actually solve public health problems.

It should also be noted that the exclusive marketing right that the patent ensures to its holder – hereby creating and guaranteeing a monopoly for a period of time – is also quite rewarding for the government and the community, since the granting of a patent requires the public disclosure of the science and technology associated with it. This public disclosure benefits the scientific community engaged in R&D of new technical drug solutions. In relation to Covid-19, the disclosure of the granted patent will foster further efficient and rapid development of new vaccines for other coronaviruses or viral mutations.

Summary

Consequently, the patent is of unquestionable benefit to the scientific community and, naturally and consequently, to the health of the world population.

Notwithstanding, the suggested alternative routes are being discussed and developments regarding their applicability should be expected. What matters the most is the rapid development of a vaccine against Covid-19, for the good of all humanity.

Author

António Andrade has been a partner at Abreu Advogados in Lisbon, Portugal since 2019, working predominantly on all matters related to IP law.

He has been particularly involved in court and arbitration litigation regarding patents (especially pharmaceutical patents), trademarks, designs, copyright and trade secrets, having built up experience over more than 20 years.