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**FREEDOM TO OPERATE – GENERAL METHOD ASSESSMENT FOR HIGH-TECH MEDICINAL PRODUCTS**

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Riassunto

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During the last years, the emphasis on mRNA technologies has increased, due to their importance for different diseases. We could say that we are at the beginning of a new era, in which it is likely that numerous research groups will focus on the efficacy, the stability and the means for delivering of new mRNA drugs. This, in fact, is noticeable not only in the wave of scientific and technical publications on this subject, but also in an upswing in the number of patent applications related to these technologies. In this scenario, searchers working on potential new RNA- inventions are strongly suggested to carry out a Freedom to Operate (FTO) analysis in order to understand if the new invention will interfere with patents of third parties.
Furthermore, all the new high-tech biological drugs, such as for example the mRNA vaccines, normally consists of a high number of structural components. So, its manufacturing and quality analysis also need many sophisticated techniques and tools normally available in the specialized field but often protected by patent rights. Yet, the observed race to file bulks of new patent applications could produce in the next future an unmanageable jam of patent-rights resulting in many litigations and lawsuits among old and new I.P. rights.
**So, what is a "freedom to operate (FTO)" assessment?**
Whenever a company is planning to develop and launch on the market a new product, a major risk, particularly in technology sectors where there is extensive patenting, is that commercialization may be blocked by a competitor who holds a patent for a technology incorporated within that product. The FTO assessment is an analysis aimed at identifying patent rights liable to hinder the marketing of a new product in a given geographical area. Thus, this assessment is carried out for the purpose of avoiding the excessive costs of legal proceedings for patent infringement or of a forced withdrawal of the product from the market.
An FTO assessment typically involves the following steps: 1) Identify key technical features and the components of the product object of the FTO and the means necessary for its production and analysis; 2) conduct a patent search based on the identified features, components and means of the product; 3) analyse if the product or any of the components and means fall within the scope of protection conferred by the claims of any earlier patent or patent application identified by the FTO search.
According to the "**mRNA Technologies, insight report, October 2023**", published by EPO, the number of international patents for all the different technological fields has increased, but the number of patents related to mRNA vaccines has almost doubled. Therefore, it's expectable that these circumstances will strongly raise the number of patent litigations. By way of example, we make reference to the case of COVID-19 mRNA vaccines, disclosed in our analysis. We understand that, despite the robust patent portfolio on mRNA vaccines owned by all the players, BioNTech, /Pfizer and Moderna would not be allowed to produce and place on the market their respective vaccines unless upon obtaining many licenses from third parties. The applicability of the analytical model proposed in the present work is not limited to the present anti-COVID mRNA vaccines, as they find a wide application in the prevention and treatment of viral and bacterial infections, cancer, and malaria. The manufacturing and the exploitation of all future mRNA vaccines or any other biotech containing mRNA-based drugs will face the same technical problems of efficacy, stability, immunogenicity and administering means as now encountered by the COVID-19 vaccines. Finally, the same analytical approach proposed in the current paper is likely to be relevant also for other emerging technology in the pharmaceutical field such as the drugs based on the CRISPR-Cas9 technology or the CAR-T Cells.

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