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***RESEARCH ARTICLE***

# Formation of patent strategy at all stages of biosimilar development and Implementation

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## ABSTRACT:

The aim of this study is to analyze the specificities formation of patent strategy at all stages of biosimilar development and implementation. Due to the complexity of biological medicinal product structure and the impossibility of accurate reproduction of technology, biosimilar can not be identical to a copy of the original biological medicinal product. The dependence of biological medicinal product from living cells, the functions of which inevitably vary, as well as the presence of impurities can significantly change the properties of biological medicinal product of different manufacturers. On the basis of the above, it follows that when creating a biosimilar there is a possibility of obtaining a new invention. It has established the possibility of biosimilar patent protection at all stages of the life cycle depending on the stage of preparation of registration dossier. It contributes to rational management of the intellectual capital of pharmaceutical companies and more effective drug provision of the population. It has been proved that various stages of the development and implementation of biosimilars should be accompanied by different types of their patenting (pharmaceutical composition, new dosage form, delivery method, optimization of the purification process, increase of stability, new indications for application or new treatment), etc. It has proposed author's algorithm for the formation of patent strategy of biosimilar development and implementation depending on the stage of preparation of the registration dossier.

**KEYWORDS:** Biosimilar, registration dossier, patent, strategy.

## INTRODUCTION:

The world market of biological medicinal products is actively developing. According to «GBI Research» company today the sales of biological medicinal products are about $200 billion. USA is accumulating an average of 17-20% of the global pharmaceutical market [1].

According to the directive of the European Parliament and the Council of the European Union 2001/83/EC, biological medicinal products include: immunological drugs; drugs are obtained from donor blood and donor plasma; medicines are obtained with the help of biotechnological processes; medicines of advanced therapy (gene therapy preparations, somatic cell therapy drugs, tissue therapy products).

Biological medicinal products have opened new possibilities for the treatment of diseases that are difficult to treat: oncological pathology, diabetes, multiple sclerosis, etc., resulting in a significant

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