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Health for all and patents on medicines: The major drift

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ACRONYMS AND ABBREVIATIONS

TRIPS	Trade-Related Aspects of Intellectual Property Rights
MA	Marketing authorization
ANDA	Abbreviated new drug application
SPC	Supplementary protection certificate
ECHP	Economic Committee for Health Products
WTO	World Health Organization
PUF	Presses universitaires de France
TEC	Treaty of European Communities
TFEU	Treaty on the functioning of the European Union.
RMCUE	Revue du marché commun et de l'Union européenne

WIPO	World international property organization

INTRODUCTION

The gap between health for all and the imperative of profitability of patents on medicines is enormous.

In day-to-day operations, the decisive question of knowing the best choice between Health for all or profitability of intellectual property linked to patents in the pharmaceutical industry is a very tricky question.

The answer to this question is far from unanimous. It varies according to various paradigms; the variables change depending on the group to which one belongs (pharmaceutical companies; State; average citizen; philanthropist, etc.).

The global health crisis linked to the Covid 19 epidemic has highlighted the fight between health for all and the issue of intellectual property linked to patents in the pharmaceutical industry.

The WTO decision of June 17, 2022, cast a chill in the pharmaceutical sector.

The authorization granted to developing States to be able to lift patents linked to Covid vaccines for five years has not only made people happy.

Continuing discussions on the extension of the TRIPS Decision to treatments and diagnostic tools will not help matters between the different opposing camps.

The inequalities in access to vaccines between the countries of the North and those of the South have reinforced the « capital importance » of the patent in the current era. The health of individuals and the imperative of profitability of patents are not always compatible.

However, the aim of medicine is to ensure and preserve the health of individuals both preventatively and curatively. Article L 5111-1 of the French Public Health Code sees it as: « any substance or composition presented as having curative or preventive properties with regard to human or animal diseases, as well as any substance or composition that can be used in humans or animals or which can be administered to them, with a view to establishing a medical diagnosis or restoring, correcting or modifying their physiological functions by exerting a pharmacological, immunological or metabolic action ».

In the pharmaceutical sector, the expiration of the patent, this industrial property title whose purpose is the protection of inventions and medicines; brings out various strategies on the part of firms.

When drug patents expire, generics invade the market. They bode well for the taxpayer and for social security. From now on, drug prices are very attractive. However, this does not come without corollaries for firms holding patents on original products. The drug research and development cycle are a long, complex, and very expensive process. The stages of development of this health product are generally: exploratory research, preclinical tests, and clinical research[1].

These stages are specifically characterized by:

- Production of the selected molecule (active ingredient) in satisfactory quantity, respecting a certain number of quality and purity criteria.
- Then: testing the drug candidate, to evaluate its effectiveness and adverse effects (preclinical studies). This involves studying the fate of the drug in the body and its interactions with the body, in

1-Pouteau Laureline, *Evolution des stratégies Marketing des laboratoires pharmaceutiques face à l'émergence des génériques sur le marché de ville en France* ; Université de Paris 11, Faculté de Pharmacie de Chatenay Malabry, 2010, p 13.

particular its effectiveness (pharmacology) and its possible toxicity (toxicology).

- ❖ Subsequently, it is a question of making the molecule administrable in a suitable form (capsule, tablet, solution for injection, patch, syrup, suppository, cream, etc.) by combining the active ingredient with excipients.
- ❖ Then, it is appropriate to continue to monitor adverse effects and seek to optimize the doses that will be administered in the first clinical studies.
- ❖ Finally, if the preclinical stages are satisfactory, the drug will be tested on humans, as part of clinical trials.

This last step: the human testing phase takes place in four phases:

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The gap between health for all and the imperative of profitability of patents on medicines is enormous.
This work highlights the eternal conflict between health for all and the imperative of profitability of intellectual property linked to patents on medicines in the pharmaceutical industry. Health for all is difficult to reconcile with the need for patent profitability. Obtaining a patent for a drug rhymes with an obligation of profitability. The expiration of the patent on the drug generates strategies on the part of pharmaceutical companies that are not in the service of health. Does health have a price?

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