Research on evergreening patents in Ukraine

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Background

There is an active discussion in Ukraine and worldwide on the impact of patent protection on the affordability of medicines and in particular ARV drugs. Big multinational pharmaceutical companies claim that patent protection should be as broad as possible as it allows to swiftly bring innovative products to the market, while their opponents from the civil society organizations refute that argument by stating that excessive patent protection restricts access to affordable treatment. In order to test this hypothesis, 100% Life, the biggest community-led organization in Ukraine launched an evergreening study, with support from Aidsfonds and ITPC Global.

Methods

The researchers selected 132 patents. Selection of patents was based on:

1. medicines that are procured from a single source in Ukraine and which are expensive due to the patent protection and
2. prospective medicines for which competition is blocked because of patents.

The next step of the research was to determine the percentage of the patents that could be defined as evergreening, i.e. patents that are granted to prevent generic competition rather than to protect genuine inventions (UNDP, 2016). The researchers used criteria set in guidelines developed by the UNDP, WHO, UNCTAD and ICTSD in order to determine whether a certain patent could be considered as evergreening.

Results

The analysis was published in 2020 and demonstrated that 60 of 132 (45.45%) patents could be considered as evergreening.

Diagram 1

The most common type of evergreening patents was a composition/dosage from the known active substance (13), isomers and salts (11), polymorphic forms (11) and the combination of the known substances (9). Of the evergreening patents the majority were related to HIV treatment (15), followed by oncology (10), rheumatoid arthritis (6) and viral hepatitis (6).

Diagram 2

The identified 60 «evergreening» patents have the following distribution by the objects of patenting:

- 11 patents: polymorphic forms (crystalline)
- 13 patents: a composition which includes a known active substance (or dosage form of a known active substance)
- 1 patient: a form of application (aqueous solution)
- 1 patient: a modified molecule (pegylated interferon)
- 1 patient: prodrugs
- 5 patients: a method of synthesis (including intermediates)
- 8 patients: a method of treatment

The research was an important argument that persuaded stakeholders in Ukraine to adopt legislation aimed at the reduction of unmerited patents in the summer of 2020. The methodology of the research could be used in other countries to measure percentage of evergreening patents.