REPURPOSING STRATEGIES

YES

NO

DRUG DEVELOPMENT OPTIONS

PHASE 1

A generic compound can be tweaked to create a new formulation and filed for a new composition-of-matter patent. Development of the reformulated compound would require an initial Phase 1 safety trial.

PHASE 2/3

Researchers can collaborate with the drug's manufacturer or license the compound from the company to test in late-stage trials for a new indication.

Alternatively, a generic drug that has already passed Phase 1 safety testing can be tested by anyone in late-stage trials until there is enough evidence for a new use, either on an off-label basis or FDA approval for a novel indication.

RELATIVE INDUSTRY INTEREST

HIGH

MEDIUM

LOW

TYPES OF PATENTS IN THE U.S.

PATENT STRENGTH

METHOD OF USE

Covers the use of a drug to treat a certain disease. This type of patent can be much more easily circumvented and is generally weaker than the composition-of-matter patent for a drug that is already approved for an indication. A method-of-use patent can be relatively strong only if it applies to an unapproved drug.

FORMULATION USE

Patent exclusivity for a delivery method and a range of doses that can be applied to a specific drug or a class of drugs. Can also cover a general formulation technology applicable to many different drug types, such as slow release or transdermal patch drug delivery.

COMPOSITION OF MATTER

Granted for a new chemical compound and provides 20 years of patent protection. This is the strongest type of patent.

PATENT VERSUS EXCLUSIVITY

Patents: Granted by the US Patent and Trademark Office (or an analogous agency in another country). Patents generally last for 20 years.

Exclusivity: Granted by the FDA upon drug approval. Exclusive marketing rights, which range from six months to seven years, give a manufacturer sole promotion rights of a drug for a certain indication as an incentive for drug innovation and prevention of generic drug competition.

Off-label drug use: When a drug is used in a different disease, administered in a different way or at a different dose than what has been specified in the drug's label (based on clinical trial data reviewed by the FDA for approval). Any drug on the market can be prescribed on an off-label basis at doctors' discretion.