**Reducing Patent Thickets and Evergreening in the U.S. Patent System**

New innovative drugs and new innovative syringes deserve patent protection. In contrast, combining an already patented drug with multiple versions of a syringe simply extends patent duration. Similarly, making obvious formula changes such as an extended release version or adding generic compounds to an existing patented drug routinely extend patent terms. These efforts not only increase drug prices for all Americans, but also violate the constitutional basis for the American patent system – to promote the progress of science and the useful arts. Repeated patent filings on the same underlying drug should be used for real innovation such as new clinical indications, not for extended patent protection on the original indication.

For example, on February 26, 2019, the CEO of AbbVie testified about the 200+ patent applications and 100+ patents surrounding Humira, several of which combine Humira with an injection device. Efforts to develop patent thickets are created not only by patent applications with endless varieties of syringes, but also by varying dosages and combinations with generic products. The Court of Appeals for the Federal Circuit in *Neptune Generics, LLC v Eli Lilly & Company.* 921 F.3d 1372 (Fed. Cir. 2019) recently delineated an important test to distinguish true innovation from obvious combinations with generic compounds and this test is incorporated into the legislation.

To ensure that real innovation is rewarded with a patent, a new 35 U.S.C. §103(b) provision would effectively require separate patent applications for compounds, delivery methods, dosing, and, subject to the test identified in *Neptune Generics*, additions of generic compounds by deeming combinations obvious. A savings clause ensures that existing patent standards for non-combination drugs remains in place to ensure that truly inventive creations which can stand on their own will still receive a patent.

Patents obtainable under current law Patents obtainable under modified 35 U.S.C. §103

Drug compound “A” Drug compound “A”

Drug compound “A” + Syringe style “1” Syringe style “1”

Drug compound “A” + Syringe style “2” Syringe style “2”

Drug compound “A” + Syringe style “3” Syringe style “3”

Drug compound “A” + Dosage “1” Dosage “1”

Drug compound “A” + Dosage “2” Dosage “2”

Drug compound “A” + Dosage “3” Dosage “3”

Amended U.S.C. §103 Conditions for patentability; non-obvious subject matter

*(changes in italics)*

(a) *IN GENERAL* - A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

*(b) PRESUMPTION WITH RESPECT TO CERTAIN CHANGES TO DRUGS AND BIOLOGICAL PRODUCTS.—*

*(1) Definitions.—In this subsection:*

*(A) Biological product.—The term ‘biological product’ has the meaning given the term in section 351 of the Public Health Service Act (42 U.S.C. 262).*

*(B) Covered claimed invention.—The term ‘covered claimed invention’ means a claimed invention that—*

*(i) contains or uses a drug or biological product that is prior art; and*

*(ii) is different from the prior art only with respect to—*

*(I) a dosing regimen for the drug or biological product described in clause (i);*

*(II) a method of administration or delivery for the drug or biological product described in clause (i);*

*(III) a method of treatment using the drug or biological product described in clause (i); or*

*(IV) a pharmaceutical formulation including the drug or biological product described in clause (i).*

*(C) Drug.—The term ‘drug’ has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).*

*(2) Presumption.—For the purposes of subsection (a), with respect to a covered claimed invention, there shall be a presumption, which the applicant with respect to the covered claimed invention may rebut, that the differences between the covered claimed invention and the prior art are such that the covered claimed invention as a whole would have been obvious before the effective filing date of the covered claimed invention, as described in that subsection.*

*(3) Rule of construction.—Nothing in this subsection may be construed to affect the conditions for patentability with respect to any claimed invention that is a drug, a biological product, a dosing regimen or method of administration for a drug or biological product, a method of treatment using a drug or biological product, or a pharmaceutical formulation including a drug or biological product if the patent application with respect to the claimed invention claims only that drug, biological product, regimen or method of administration, method of treatment, or formulation, as applicable.*