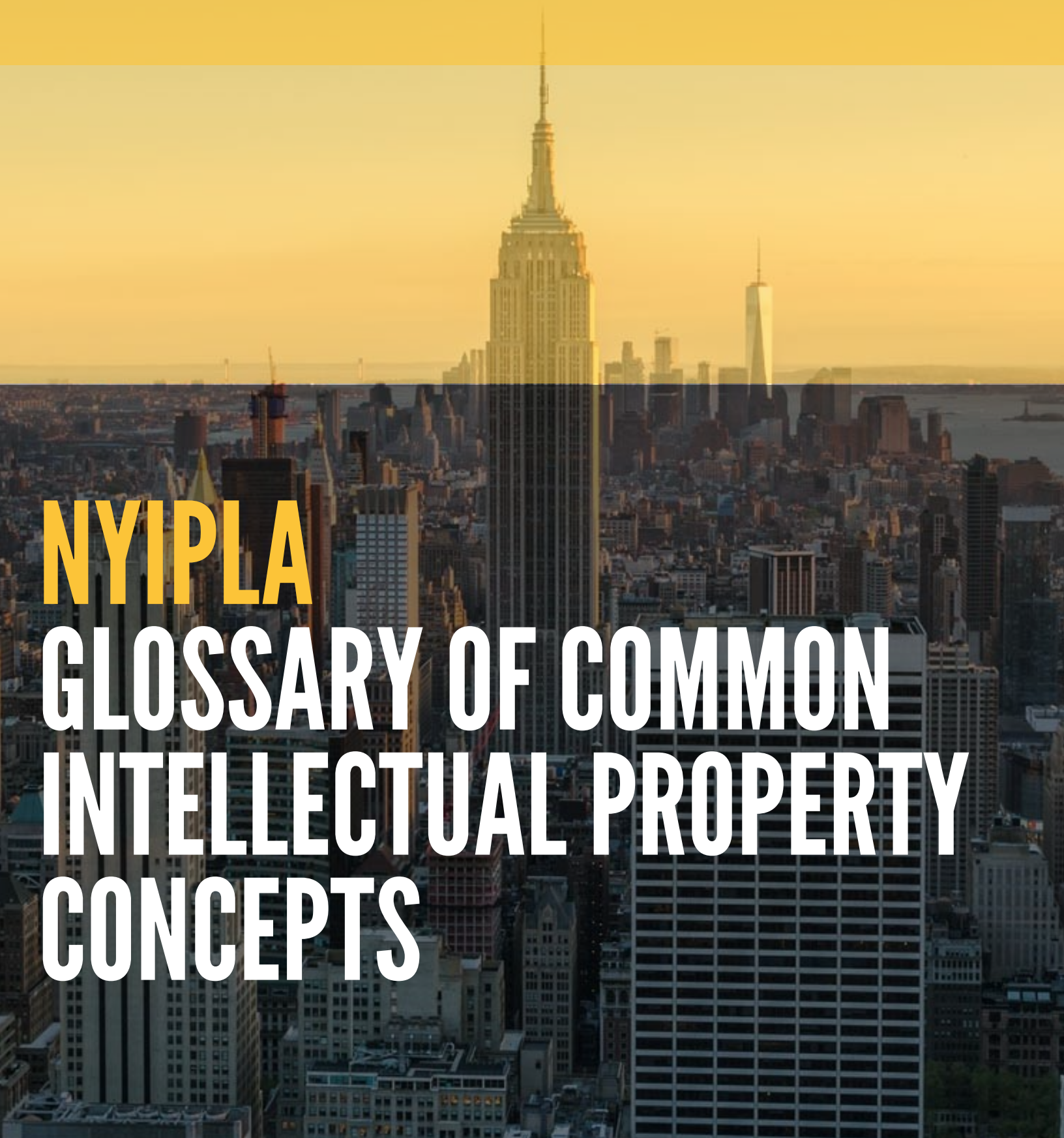
Nineteen Hundred and Twenty-two

NYIPLA

The New York Intellectual Property Law Association®



NYIPLA GLOSSARY OF COMMON INTELLECTUAL PROPERTY CONCEPTS

ABOUT US

On March 7, 1922, the New York Patent Law Association was conceived as an organization through which patent lawyers in New York could make their views known in Washington and provide support for the judiciary. The Association, presided over by William Houston Kenyon, immediately launched into an ambitious program of activities, including the support of the Lehlback Bill, the investigation of post-war revival of the Patent Treaty with Germany, and the encouragement of improvements in the quarters of the federal courts in New York City.

The NYIPLA currently serves as a vehicle to promote the development and administration of intellectual property interests. NYIPLA strives to educate the public and members of the bar in this particular field and continually works with foreign associations to harmonize the substance and interpretation of international conventions for the protection of intellectual property.

MEDIA & REUSE POLICY

All media, project inquiries, and content questions should be directed to the NYIPLA Executive Office. For more information on NYIPLA legislative action activities, visit us online at www.nyipla.org. Please contact the NYPLA Executive Office before transmitting or reproducing this publication.

CONTACT US

New York Intellectual Property Law Association (NYIPLA)
2125 Center Avenue, Suite 406 | Fort Lee, New Jersey 07024
Tel (201) 461-6603 | Fax (201) 461-6635
Web www.nyipla.org | E-mail admin@nyipla.org

CONCEPTS FROM OR RELEVANT TO PROPOSED PATENT LEGISLATION

In the process of reviewing proposed and pending federal and state legislation relating to patents, members of the NYIPLA have noticed that certain legislation uses several terms (such as "patent thicket/thicketing;" "composition of matter patent;" "patent family;" and "patent portfolio") differently than they are in the every-day practice of patent law. The NYIPLA sets for the below terms the way those terms, and other relevant terms, are commonly used in the practice of patent law and understood by members of the patent community.

Patent Thicket

A patent thicket is formed when a group of overlapping patents or patent estates covers a product, process, or technology in a specific industry, and could be owned by a single company, a family of companies or a group of unrelated companies. Often a company that would like to make a competing product may need to approach several companies and need rights from all those companies to bring a product to market. Patent thickets have been known to occur in the "tech" space with, e.g., smartphones that may embody technology covered by the patent portfolios of several companies.

Patent Portfolio/Patent Estate

A patent portfolio is a collection of individual patents and patent applications that share critical technological features owned by one company and/or its affiliates. For example, a patent portfolio may focus on solutions to a particular problem in an industry, the development of a particular process (methods of treating a disease or disease group), or the features of a particular product (such as consumer electronics). Often a patent portfolio can cover several aspects of a product. A coherently designed strategic collection of patents owned by the same entity, the patent portfolio confers an array of important advantages upon the portfolio holder.

Patent Family

A collection of published patent documents relating to the same technical disclosure involving prosecution of the patent applications in the same country or in different countries or regions. Each member of a patent family typically has, as the basis of its "priority right," at least one originating application in common with the other members of the family. Below are types of patent families common in the biopharmaceutical industry.

- **Composition of Matter Patents** – These types of patents tend to cover a composition of matter such as a drug substance (e.g., the active ingredient), the drug product (e.g., the final product taken by or administered to a patient).

- **Device Patents** – These patents cover devices that deliver or administer the drug product or regulate its dosage for delivery to a patient.
- **Compound Patent/Active Moeity Patents** – These patents are a subset of composition of matter patents that cover the active ingredient in drug products (e.g., the chemical compound). Often these patents can cover several compounds and can lead to a family of patents covering various chemical compounds.
- **Salt Patents** – These patents are a subset of Composition of Matter Patents and cover a specific chemical salt form of the active ingredient used in the final formulation and are often (but not always) members of the same patent family as the Compound Patents.
- **Polymorph Patents** – These patents are a subset of Composition of Matter Patents that cover the three-dimensional arrangement of drug molecules. Often these come from a separate family of patents as the Compound Patent and result from further innovation as a company is bringing a medicine to market.
- **Formulation Patents** – These patents are a subset of Composition of Matter Patents that cover the formulated ingredients that are included in the actual product that is administered to the patient. Often these are a separate family of patents from the Compound Patent and result from further innovation as a company is bringing a medicine to market.
- **Method of Treatment/Method of Use Patents** – These are not Composition of Matter patents and cover methods of using a drug substance or drug product to treat a particular illness or condition. These may be separate families of patents and result from further research, innovation and clinical trials run by a company.
- **Process Patents** – These are not Composition of Matter patents. These patents cover processes for making the drug substance and often result from innovation in optimizing the process for bringing a drug product to market.

Evergreening

This term is used to describe the practice of obtaining ancillary pharmaceutical patents that allegedly do not represent true innovation to extend the marketing lifecycle for pharmaceutical products involving a particular chemical compound. Sometimes, obtaining and/or enforcing the types of patents listed above (e.g., salt patents, polymorph patents, method of treatment patents) have given rise to allegations of evergreening. In the NYIPLA's experience, such allegations must be taken on a case-by-case basis to make distinctions between true innovation and trivial changes to drug products to extend the duration of patent protection. These later-issued patents do not extend the term for the initial compound patent itself, but they do extend the period of time when the drug maker can exclude generics from the market for formulations containing that compound.

Product Hopping

A term that refers to a drug maker moving its customers from one branded drug to another, very similar drug covered by newer patents that expire later, thus extending the drug maker's patent-protected market exclusivity. Product hopping occurs when a drug maker discontinues an old formulation of a drug whose patent expiration date has passed or is approaching and in its place markets a more recently patented formulation involving that same or very similar drug. After the old patent's expiration, competitors are free to use the drug's formula to manufacture generic versions as a cheaper option. Often, once the patent for the old formulation of the drug expires and generic versions become available, users have become reliant on the new formulation of the drug. If the new formulation has a different dosage, strength, or delivery mechanism than the old formulation, most state drug substitution laws prevent pharmacists from replacing the new formulation with generic versions of the old formulation.

CONCEPTS FROM OR RELEVANT TO PROPOSED SETTLEMENT LEGISLATION, INCLUDING S. 64

In the process of reviewing the various proposed bills addressing pharmaceutical patent settlements, members of the NYIPLA have noticed that the proposed legislation refers to concepts common to the practice of settling patent disputes. The proposed settlement legislation seems to deem these common concepts and provisions to be presumptively anti-competitive. The NYIPLA encourages Congress to consider whether the concepts below along with the current list of "exclusions" in Section 27 (c) of S.64 should be evaluated to determine if a settlement is pro-competitive prior to applying any presumption of anti-competitiveness as called for in the currently proposed patent settlement legislation.

Reverse Payment/Pay-for-Delay

A payment from the brand pharmaceutical company to the generic challenger to settle Hatch-Waxman litigation is called a "reverse payment." In the classic sense, a "reverse payment" is often an unjustified, large sum of money or other compensation paid to a generic manufacturer to delay launch of a generic product. More recently, provisions where the brand company agrees not to introduce or authorize the introduction of a generic product have been considered a form of non-cash reverse payments. Settlements including "reverse payments" are referred to as pay-for-delay agreements to the extent that they postpone the generic firm's entry on the market to a date later than the generic company asserted in litigation that it should be able to launch if the patents in question are either not infringed or valid. The proposed legislation and the current discourse around drug pricing is using the term "pay-for-delay" to refer to all biopharmaceutical patent settlements. In the experience of the NYIPLA, such a use of the term is too broad and covers the vast majority of settlements that do not involve a large, unjustified payment in exchange for a delay in generic drug entry.

Anything of Value

This term is used loosely in the various proposed legislation regarding the settlement of biopharmaceutical patent disputes, including in S. 64. It is unclear what the bill means by anything of value, and it seems that the FTC may consider the underlying patent license itself to be something of value. [1] The NYIPLA believes that this term needs to be narrowly defined so that the underlying patent license and other common, pro-competitive terms are not considered to be "anything of value" or compensation to the generic manufacturer.

Effect of Common License Provisions

The term "anything of value", discussed above, if defined and/or applied too broadly runs the risk of ensnaring certain provisions common to biopharmaceutical patent settlements as being improper "compensation" from the patent holder to the generic manufacturer.

- **"Accelerators"** – In the experience of the NYIPLA and its member patent practitioners, settlements in the biopharmaceutical arts often contain certain provision that can accelerate the base license date agreed to by the party. These "accelerators" or acceleration clauses often lead to earlier generic entry and, in the opinion of the NYIPLA, should be presumptively viewed as pro-competitive. Common accelerators included in biopharmaceutical patent settlement agreements include launch of generic product upon: invalidation/cancellation/delisting of the patents; third party launch of another generic product; launch of an authorized generic product by the patentee or a third party; and a decline in the market share for the brand-name product.
- **"No-Discontinuance Clauses"** – Often biopharmaceutical patent settlement agreements include clauses that the brand-name company cannot discontinue the reference-listed product (e.g., by cancelling NDC codes or withdrawing the NDA) until there has been a generic launch. In the experience of the NYIPLA and its members, these clauses are often pro-competitive and allow generic manufactures to contract around so-called "product-hopping" in order to ensure launch of a generic product pursuant to the settlement agreements.
- **"Licenses/Covenants Not To Sue on Future Patents"** – Often biopharmaceutical patent settlement agreements contemplate further innovation on the part of the brand-name manufacturer and provide for generic entry even if there are new patents obtained and/or listed in the Orange Book after the execution of the settlement agreement by providing licenses or covenants-not-to-sue on later-acquired patents. In the experience of the NYIPLA, these clauses help ensure generic entry as of the settlement date and prevent a lawsuit on later-acquired patents that would otherwise make a settlement illusory. These types of clauses should be generally viewed as pro-competitive and not an unjustified payment inducing a delay in generic entry. These types of clauses also provide broad protection for a generic manufacturer against large patent portfolios or "thickets" as they have been called in other draft legislation.

[1] At the April 29-30 annual ACI PIV Disputes seminar, the FTC gave a presentation in which it listed the underlying patent license itself as anything of value/possible compensation paid to the generic.

- **"First patent"** (as that term is used in H.R.3199) – 'Terminating the Extension of Rights Misappropriated Act of 2019'' or the ''Term Act of 2019''.

  The term "first patent" is used in Sec. 2(a) of the bill: "the patentee shall be presumed to have disclaimed the patent term for each of the listed patents after the date on which the term of the first patent expires."

  No definition of the term "first patent" is provided in the bill. "First patent" is not a standard IP term of art (i.e., there is no established or consensus definition for this term).

  Concerns: This could be interpreted in any number of ways, including that the patentee is presumed to have disclaimed patent term for all of its Orange Book-listed patents, as of the date on which the first of the Orange Book-listed patents expires. Or, conceivably, this could be interpreted to mean that there is a disclaimer as of the date the earliest of the patentee's patents directed to the product expires, among other possible (albeit less-plausible) interpretations.