CONTRACTS IN THE PHARMACEUTICAL INDUSTRY: TYPES AND CLAUSES

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ABSTRACT

The Pharmaceutical Industry is one that is involved in the discovery, research, development, production, marketing, and sale of pharmaceuticals. India currently holds the position of the 3rd largest producer of pharmaceuticals by volume with an Annual Turnover of more than 2 lakh crores. Various stakeholders including Manufacturers, Pharmacies, Medical Professionals and Consumers enter into innumerable number of transactions on a day-to-day basis. This short article seeks to explore the various types of Contracts that may be entered into by the various stakeholders in the Pharmaceutical Industry not only in India but Internationally, and also the types of Clauses required to be covered therein.

The Pharmaceutical Industry as it stands today, is a multibillion-dollar industry that involves a multilayered and complex web of organizations, systems, and products that work in unison to research, develop and deliver pharmaceuticals, or medicines, to those in need. Over the past century, the pharmaceutical industry has evolved into one of the most developed industrial sectors, with its growth being fueled by rapid advancements in science and technology.

With the advent of such growth also comes the need for a robust and intricate legal system that would serve the govern the plethora of transactions and processes that take place on a day-to-day basis. It is for this reason that Pharmaceutical Contracts require the utmost level of care and caution while drafting, by reason of the stakes involved being at such a high level. Clauses such as Confidentiality and Non-Disclosure, Intellectual Property Licensing, Indemnity and so forth must be drafted with precision, keeping in mind the goals of the Client and any future contingencies that may arise subsequently. The present article thus enumerates the various types of contracts that are implemented domestically and internationally, and provides a short overview of the main Clauses to be included in such documents along with a description of each Clause.

"Medicine is not only a science; it is also an art. It does not consist of compounding pills and plasters; it deals with the very processes of life, which must be understood before they may be guided." – Paracelsus.

Pharmaceutical Contracts: An Overview

A Contract may be defined as a binding agreement between two parties that is enforceable by law and creates, outlines, and administers mutual rights and obligations between said parties.

Pharmaceutical Contracts may include Contracts between various stakeholders such as Pharmaceutical Companies, Healthcare Sectors, Private Practitioners and Consumers for the sale, distribution, use, testing, research, advertisement, and manufacture of medicines. These Contracts must abide by multiple laws and guidelines concerning various aspects of the distribution of such pharmaceuticals. A common sector that often relies on such agreements are the Contract Development and Manufacturing Organizations, or CDMOs, which provide services to pharmaceutical companies including development and manufacturing of pharmaceuticals on a contractual basis. A study by the Indian Drug Manufacturers' Association[1], India currently leads the pharmaceutical markets internationally with a growth rate of 20 % and a market value of roughly US$ 5.3 bn.

Various types of contracts and agreements may thus come into play in the industry, which are discussed below.

Types of Pharmaceutical Contracts

Some of the basic types of Contracts that may be entered into in the Pharmaceutical Industry include:

1. **Equipment and R&D Licensing:** These involve Contracts wherein an interested party contracts to obtain the use of certain Equipment from a Company in possession thereof. Such Equipment may include various tools, implements and machinery that are used in the manufacture and production of Pharmaceutical Drugs. Additionally, Research and Development is one of the primary areas of focus for any Pharmaceutical Company, as it leads to new innovations and products based on

[1] Pharmaceutical Contract Development and Manufacturing Market (Pharmaceutical, Biologics, Active Pharma ingredients, tablet, Parenteral, Oral Liquid, Semi-Solids), End User (Big Pharma, Small Pharma, Generic Pharma, CRO)-Global Forecast to 2026.

emerging knowledge and technology. Licensing allows companies to access knowledge and technologies developed outside their organizational boundaries.[2] In recent times, Companies have begun to license such R&D from other well establish Pharmaceutical Companies in order to cut down on expenses and also benefit from the extensive resources possessed by the Licensors.[3]

2. **Intellectual Property Licensing:** This is an agreement between holders of certain IP Rights including Patents, Trademarks, Designs and Copyrights, and third parties who wish to use such IPs for a limited period of time. Such third parties, called licensees, obtain the License from the IP holders, termed Licensors, for a specified period and a certain geographical area. In Pharmaceutical Contracts, such IP may include Trademarks for medicine brands, patented formula, Manufacturing Equipment Designs and Methods of Production among others.
3. **Outcomes Based Contracts:** These are value-based contracts which tie actual patient health outcomes to drug reimbursement and provide blueprints to payers for cutting costs of prescription drugs through proactive management of chronic patients. Value based contracts are those which provide the option of lowering prices of pharmaceuticals whilst improving outcomes for patients, thus ensuring that the consumers receive the greatest amount of benefit through the medicines they purchase. Along with Cost Cap Contracts and Indication Based Management Contracts, these are generally entered into by CDMOs whilst providing various pharmaceutical related services.
4. **Cost Cap Contracts:** These contracts come into the picture when a new pharmaceutical enters the market at a higher price than similar drugs. In such cases, the pharmacies negotiate a maximum per member per month cost of a drug with the manufacturers, which promotes market competition and lowers costs of prescription drugs.
5. **Indication Based Management**: Such contracts determine the intrinsic value of pharmaceuticals through the relative costs of the recipients' health conditions, such as costs associated with a chronic disease. Such contracts ensure that specific drugs reach

[2]Arora A (1995) Licensing tacit knowledge: Intellectual property rights and the market for know-how. Econom. Innovation New Tech. 4(1):41–60.
[3]Moreira, Solon; Klueter, Thomas Maximilian; Tasselli, Stefano (2020). Competition, Technology Licensing-in, and Innovation. Organization Science, (), orsc.2019.1337

their intended end consumers with specific conditions. Such contracts include benefits such as minimization of costs and maximization of patients' health outcomes.

6. **Lease Deeds:** Lease Deeds involve contracts between the owners of immovable properties (the Lessor) and individuals who wish to occupy, and use said properties (the Lessee). These are similar to Rental Agreements that may be entered into by a landlord and his tenant but are generally executed for longer periods of more than a year. The properties may include factories and warehouses for the production and storage of pharmaceutical goods.
7. **Collaboration and Joint Venture Agreements:** Joint Venture Agreements are those in which two or more parties enter a contract to combine their resources to complete a certain task. In such arrangements, every participant is responsible for any profits, losses or other costs associated with the venture, which is distinct from the parties' individual businesses. Through such arrangements, parties get benefits such as leveraging of resources, saving on costs, combining expertise and know how, and obtaining entry into foreign markets.
8. **Invention Assignment Agreements:** Such Contracts are generally entered into by an Employer with his/her employees, who allow the former to obtain rights to any inventions that may be created or developed by them over the course of their employment. These types of agreements generally require the employees to voluntarily disclose any and all such inventions to their employers and to assign rights of ownership to them. In addition to the standard boilerplate clauses, such contracts may also include provisions requiring employees to disclose pertinent details of all inventions made by them prior to the commencement of their employment, so as to prevent them from later claiming that future inventions were made by them prior to the course of their employment. A waiver provision is also generally included wherein the employees waive any rights that may arise out of the invention.
9. **Credit Agreements:** These are legally binding contracts that outline the terms of a loan agreement between two parties, i.e., the lender and the borrower. They enable the borrower to utilize the funds provided by the lender for retail or institutional purposes. Oftentimes, Pharmaceutical Companies may enter into such agreements with VCs and Investment Banks in order to fund their Manufacturing and R&D Projects.
10. **Quality Agreements:** Quality Agreements are Contracts that specify and outline certain quality parameters for a given project, in addition to details of the parties responsible for the execution of said parameters. These Agreements are generally

implemented when a Contract Development and Manufacturing Organization is employed by a Pharmaceutical Company, who include in the agreement multiple aspects of the project affecting the safety, purity, quality and potency of a product, along with items that could affect the compliance status of either party.

11. **Product Supply Agreements:** As the name suggests, such agreements establish the various terms on which a seller will supply to the buyer products which the latter requires over the course of his business. This may include provisions specifying the minimum purchase quantity, contingencies for failure of purchase, exceptions, inspection, acceptance of goods and so forth.
12. **Technology Transfer Agreement:** These Agreements facilitate the transfer of technology and intellectual property from one Company to another by way of assignment or licensing. Industrial and Intellectual Property including knowhow and machinery, patents, industrial designs, and trademarks may be assigned or licensed. Such contracts often come into play in the pharmaceutical industries by companies who seek to reduce their manufacturing and R&D costs.

Some of the **Common Clauses** found in the above types of Contracts include:

1. **3rd Party Licensing & IP Rights:** Intellectual Property Rights may include rights such as Trademarks, Patents, Designs and Copyrights. Pharmaceutical Companies often enter into IP licensing contracts with 3rd parties in order to gain monetary benefits from their IP Ownership. A 3rd party licensing & IP rights clause includes a requirement for the parties to the contract to give written notice to the other, in case of an infringement of either party's IP Rights by a third party. This may include impediments on the use of the parties' licensed technology, joint patent rights & inventions, or on the manufacture, use, sale, distribution, marketing, etc. of their products. The parties may also agree on a joint course of action to be taken in such cases.
2. **Clauses of Confidentiality & Non-Disclosure:** This clause imposes an obligation on the parties or certain persons within their organization to refrain from disclosing sensitive information pertaining to various aspects of the organization to the public or any third party. It also lists the various terms and conditions of such non-disclosure, permitted disclosures and contingencies therein. These Clauses are commonly used in the competitive pharmaceutical industry whose work involves an abundance of sensitive information including formulations, methods of production and so forth.

3. **Representations & Warranties:** The Representation and Warranties clause are primary boilerplate clauses of almost all commercial contracts including Pharmaceutical Contracts. This clause includes various statements of facts, or representations, made by one party to another, which induces the second party into entering the contract. Warranties, on the other hand, are promises made by one party to another that a condition or fact asserted is true and are backed by implied promises of indemnification in the event of such assertions being false. These clauses are also used for the purposes of allowing the contractor from disclosing information and avoiding future liability, promoting good faith, and allocating risk between parties.
4. **Trademark Clause:** Trademarks are a major area of concern for Pharmaceutical Companies as they serve to identify and set apart their products and pharmaceuticals. Pharma Companies may manufacture medicines with similar chemical formulations or compositions albeit with varying trademarks and brand names, including logos, tag lines and so forth. It is thus important for Pharmaceutical Contracts to have a comprehensive Trademarks Clause that sets out the rights of each party with respect to the use, licensing, advertising etc. of the other's Trademarks.
5. **Indemnity Clause:** Indemnity has been defined as "protection against possible damage or loss, especially a promise of payment, or the money paid if there is such damage or loss."

   Such clauses include a promise or assurance made by one party, the indemnifier, to protect or indemnify the other (the indemnity holder) from losses, costs, expenses, damages or any legal implications that may arise due to the actions of a third party or the indemnifier himself.
6. **Term & Termination:** The term of a contract must be specified clearly so as to avoid confusion at a later stage. Additionally, Contracts also generally include a Termination Clause, which lists out the various conditions or scenarios in which a contract may be terminated by either party such as Non-Payment of Dues, failure to perform contractual obligations and so forth.
7. **Fee for Service & Delay Policies:** A Fee-for-Service Clause is one included in certain pharmaceutical contracts which entitles a doctor, physician, or health care provider to compensation for every service rendered or provided. This serves to reward the physicians for the quality and volume of the services they provide. Such payments are also termed as a-la-carte payments.

8. **Publications:** A publications clause imposes obligations on the contracting party to comply with any procedures established in the contract with respect to publication of documents or communications. It may seek to prevent publication of confidential documents or otherwise, including results of studies, internal investigations, and so forth except when required by law. It may also include steps to be followed prior to publication including Review, Maintenance of Standards, Voluntary Disclosures and so forth, along with conditions and liabilities therein.
9. **Limitation of Liability Clause:** As the name suggests, this Clause serves to limit a Contracting Party's liability in case of the happening of an adverse event. Such events may include failure, non-performance, breach of duties, delay etc. This is generally included in pharmaceutical contracts, as such contracts include subject matter whose value is generally quite high. The rationale for including such clauses is generally to protect the contracting party from "undertaking risk which may not be commensurate with the small fee that it may be charging for doing a particular assignment or handling an equipment."[4]
10. **Audits & Inspection Rights:** Every commercial contract includes a clause that sets out the rights and obligations of the parties with respect to timely audits and inspections. This generally includes requiring the party to permit entry of officers or auditing bodies conducting the audit into the premises, presenting all requisite materials, documents, books of accounts etc. for inspection, providing adequate workspaces and so forth. Additionally, the party is required to disclose any and all discrepancies that may be present in the accounts at the time of the audit.

Conclusion

The Pharmaceutical Industry includes a complex and interconnected web of Companies, Service Providers, Consumers, and various intermediaries who enter various transactions with each other on a day-to-day basis. It is thus necessary for Contracts between such parties to be as comprehensive and consistent as possible to minimize losses and limit liability. It is also important to maintain awareness of the rapid legal, scientific, and technical advancements that occur in the industry and incorporate them in said agreements. In today's day and age it is imperative for Pharmaceutical Companies to look beyond profit making objectives and to strive

[4] https://www.mondaq.com/india/contracts-and-commercial-law/613966/limitation-of-liability-clause-in-an-agreement

for universally affordable healthcare and wide distribution of prescription drugs. This can only be done through a robust system of licensing and cooperation wherein the holders of patent rights do not covet exclusivity and market monopoly and instead collaborate with competitors and stakeholders alike for the greater good.