

# Chapter 2

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## An Overview of Research & Development, Product Launch, and Patent Enforcement

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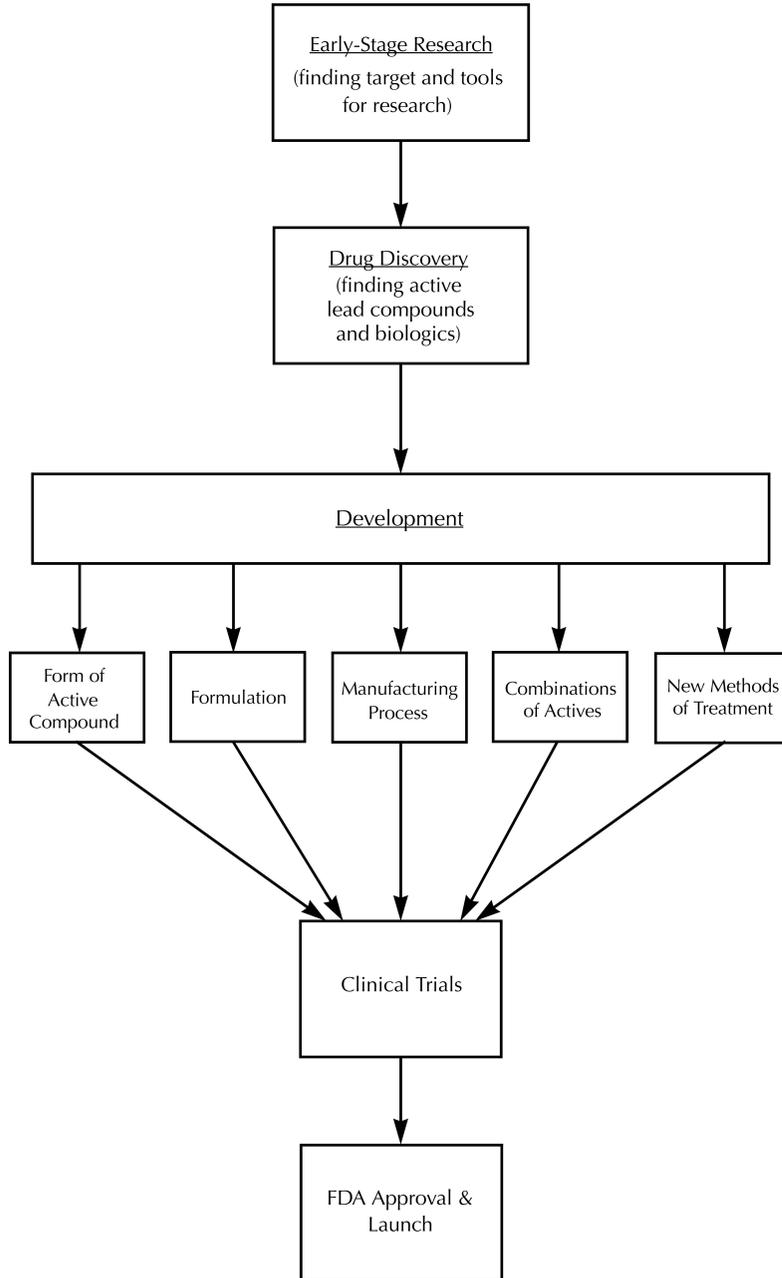
**§ 2:4.2 Clinical Trials****[A] The FDA Approval Process****[A][1] Clinical Studies and Trials****[A][2] Patent Term Restoration for FDA Delay****[B] The Hatch-Waxman Act: Generic Competition****[B][1] ANDA Litigation****[B][2] Data Exclusivity****§ 2:5 Patent Protection for Pharmaceutical and Biotech Inventions****§ 2:1 General**

The basic principles of the patent law apply equally across all types of technology.<sup>1</sup> Basic patent law principles may be general in the abstract, but when applied to pharmaceutical and biotech patents, they present recurring issues that are often unique to this field. The present chapter provides an overview of the research and development process, launching new products, and patent enforcement.

Research and development (R&D) can be broken up into several phases, as illustrated in Fig. 2-1. The steps of pharmaceutical R&D, however, are not usually performed in a simple linear sequence as depicted in Fig. 2-1.<sup>2</sup> Often different phases of R&D overlap and even circle back to prior phases because active compounds may, after further evaluation, turn out to be unsuitable as drug candidates. Furthermore, pharmaceutical R&D takes many other forms not depicted here. Figure 2-1 nevertheless provides a framework for the pharmaceutical and biotech patent issues discussed in this treatise.

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1. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1325–26 (Fed. Cir. 2003) (referring to “the technology-neutral language of the Patent Act”).
  2. The term “drug” or “pharmaceutical” refers both to traditional small molecules such as acetylsalicylic acid (aspirin) and biologics such as erythropoietin (EPO). This book also covers non-drug-based therapies and medical procedures such as use of medical devices, performance of medical procedures, and the use of diagnostics.

**Fig. 2-1**  
**Examples of Phases of**  
**Research and Development**



The research phase in pharmaceutical R&D often includes early-stage research, which involves identifying relevant biological targets and developing tools to test the activity of potential drug candidates against those targets.<sup>3</sup> Early stage research serves as the foundation for further drug discovery that involves making new compounds and evaluating them for the desired biological activities. Universities and startup companies as well as major pharmaceutical companies engage in early-stage research.

Development of a drug candidate, however, requires greater resources because it involves continued preclinical testing, devising reliable and efficient methods for manufacturing bulk quantities of the drug, formulating it in an appropriate manner to deliver the right quantities of the drug to the patient over the optimum period of time, and testing the drug in a series of human clinical trials.

The research and development needed to create a new medical treatment can span decades, involve hundreds of scientists, technicians, and managers from one or several institutions, cost tens or hundreds of millions of dollars, and, at the last moment, end in commercial failure. Yet, even partial success against major diseases can provide life-changing benefits to millions. New treatments, if protected by patent rights, can also yield substantial profits. Only the prospect of this reward can economically justify the expense and the risk of research and development.

The reward of commercially valuable patents rights, however, does not flow automatically from successful and original research. Patent rights, like the drugs they protect, usually come from execution of a carefully planned strategy. Patent planning should begin at the earliest stage and evolve with the drug discovery and development process that, with enough skill and luck, will produce a new and useful treatment.

## § 2:2 Research Teams

Increasingly, modern research and development requires teams of scientists. The chemical structure and biological characteristics of the next anti-cancer agent will likely require the sweat and brains of many. Likewise, the patent law has evolved to accommodate the existence of team-based innovation.

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3. RICHARD B. SILVERMAN, *THE ORGANIC CHEMISTRY OF DRUG DESIGN AND DRUG ACTION* (Academic Press, 1992); ANDREJUS KOROLKOVAS, *ESSENTIALS OF MOLECULAR PHARMACOLOGY* (John Wiley & Sons, 1970).

### § 2:2.1 Patent Issues Related to Research Teams

The team-based approach to drug discovery and development raises many legal questions including the following, which are addressed in later chapters:

- When does the invention occur?<sup>4</sup>
- Who are the actual inventors?<sup>5</sup>
- When does one entity's own prior work hamper the ability to obtain new patent rights?<sup>6</sup>
- When there are multiple inventors to a single patent, who owns the invention?<sup>7</sup>
- What happens to inventorship when one team uses technology or innovations made by another team?<sup>8</sup>
- What happens to patent ownership when an institution uses government-funded research to make its invention?<sup>9</sup>
- How does one safely collaborate to avoid unexpected loss of patent rights or joint ownership of resulting patents?<sup>10</sup>
- How does one define ordinary skill in the art in a field involving teams of researchers when determining obviousness?<sup>11</sup>

### § 2:2.2 Government-Funded Research: The Bayh-Dole Act

Prior to the 1980 Bayh-Dole Act,<sup>12</sup> government policy required that the federal government retain ownership in any resulting inventions for most federally funded research directed towards public health.<sup>13</sup> The Bayh-Dole Act made it possible for private institutions,

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4. See *infra* section 4:1 (inventorship).
  5. See *infra* section 4:1.
  6. See *infra* sections 5:2.1 and 5:2.3 (concerning statutory bars that prevent applicant from obtaining a patent based on categories of prior art existing a year prior to the filing date even if it is the inventor's own work); section 5:3.1[C] (co-ownership/joint venture exception to prior art: section 103(c)); section 5:8 (double patenting).
  7. See *infra* sections 4:5 (inventorship and ownership) and 4:6 (anticipating and resolving joint inventorship issues).
  8. See *infra* section 4:2 (joint inventorship); section 4:5 (inventorship and ownership); and section 12:5 (ownership of private party-government employee co-inventions).
  9. See *infra* chapter 12 (government funded research and the Bayh-Dole Act).
  10. See *infra* section 4:6.
  11. See *infra* section 5:3.6.
  12. 35 U.S.C. § 200; 37 C.F.R. § 401.
  13. See *infra* section 12:1.1.

such as universities, to own patent rights in inventions arising out of government-funded research. Obtaining rights under Bayh-Dole requires compliance with a series of regulations.<sup>14</sup> Any patent applicant who wants to obtain ownership of a patent arising out of government-funded research, or any party who wants to obtain a license under such a patent, must exercise care to make certain that the applicant has complied with applicable requirements under the Bayh-Dole Act, the corresponding regulations, and the government funding agreement.

Parties should also be aware that ownership rights in inventions obtained under the Bayh-Dole Act are not unlimited.<sup>15</sup> The government retains a non-exclusive license to make the invention or have the invention made, and certain “march-in” rights permitting the government to require the patent owner to grant a license to a responsible third party. Although these government rights, if exercised, could have a great impact on the rights to any patent subject to Bayh-Dole, so far the government has rarely, if ever, exercised its Bayh-Dole rights.<sup>16</sup>

### **§ 2:2.3      *Joint Inventions Made by Federal Employees and Private Parties***

Sometimes during the course of government-funded research, a government employee and private employee become co-inventors. Under these circumstances a federal agency may jointly own the invention along with the private party. Alternatively the government agency may license or assign its rights to the private party or acquire the private party’s rights in the invention.<sup>17</sup>

## **§ 2:3      *Research***

### **§ 2:3.1      *Early-Stage Research***

Some drugs are discovered accidentally, without any prior understanding of the biological mechanism responsible for the drug’s activity. Nevertheless, modern drug discovery efforts are increasingly predicated on some prior discovery that provides both tools for identifying potential drug candidates and a theoretical basis for understanding the drug’s mechanism of action. Early-stage research often involves the identification of a relevant biological target. It can involve identification of a new gene, receptor, or enzyme, and its biological function. It can also involve a new methodology for testing

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14.    *See infra* section 12:2.

15.    *See infra* section 12:3.

16.    *See infra* section 12:3.

17.    *See infra* section 12:5.

compounds for potential biological activity. This early-stage research often precedes the drug discovery process, but it can continue in parallel with ongoing drug discovery efforts.

Not all early-stage research, however, results directly in patentable inventions. A discovery must yield something useful to be patentable. A new compound, gene, protein, antibody or fragment without any known pharmacological activity or other practical utility, will not normally be patentable. This safeguard prevents would-be inventors who fail to provide some practical benefit to the public from blocking promising avenues of research by others. For a pharmaceutical invention to be patentable, research must progress to the point of some pharmacological activity or other identifiable utility, even if it has not been conclusively demonstrated in humans.<sup>18</sup> On the other hand, when a discovery has practical utility and satisfies the other requirements of patentability, a patent may be obtained.<sup>19</sup>

Patents based on early-stage research are sometimes directed to materials and methods used in drug research and development. These patents are sometimes referred to as “research tool” patents and often affect the ability of others to pursue further research in that area.<sup>20</sup> Research tool patents provide a way for the inventors to derive profit from their work without taking on the heavy burden of developing new treatments. On the other hand, research tool patents can present obstacles to others trying to develop new drugs that can only be overcome by licensing, designing around, conducting research outside the United States, or obtaining the benefit of the statutory safe harbor provision covering collection of data for FDA submissions.<sup>21</sup>

Even if some discoveries merit award of patent rights, the rights granted must be commensurate with the scope of the discovery. Identifying the mechanism by which some compounds achieve their pharmacological activity and the tools to identify such activity in test compounds may support claims to that research tool. It may not, however, support claims to the method of treating patients with compounds found by that research tool—particularly if no such compounds were known by the time of the invention.<sup>22</sup>

### § 2:3.2 Drug Discovery

The drug discovery process often begins with searching for a small organic molecule (in the case of traditional pharmaceuticals), or a

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18. See *infra* chapter 3 (utility).

19. See *generally* chapter 5 (Patentability).

20. See *infra* section 7:1 (research tool patents).

21. See *infra* section 7:1.

22. See *infra* section 7:4.6[B] (Field of Use Claim); see also *infra* section 5:5.5.

larger organic molecule (in the case of biologics) such as a nucleic acid or antibody that has some desired activity against a particular target in the body. Searching for such molecules usually requires an assay to conveniently test for the desired activity and a source of potentially active compounds. Once compounds are identified that have the desired activity and potency, they are often tested in a series of other assays to assess whether that activity might translate into therapeutically meaningful results and whether the compound will have all of the other properties, such as acceptable duration of action in the body and side effect profile, necessary to make it into a clinically useful treatment. Patent applications can and usually are filed on the active compounds and methods of treatment using these compounds in the discovery phase prior to development.<sup>23</sup>

Although the goal of drug discovery is to develop new treatments through extensive testing, one must be mindful that the path to such discovery may be covered by other patents that can block or impede progress. The compounds being tested, and the testing methods themselves, may be covered by patents. Congress provided some relief by exempting from infringement certain activities directed to developing data for the Food and Drug Administration to obtain certain drug approvals.<sup>24</sup> Nevertheless, not all activities are exempt from infringement so awareness of patent issues must begin with the inception of a research program. To illustrate the development process, we focus in the next section on development of small molecule drugs.

## § 2:4 Development

### § 2:4.1 Preclinical Development

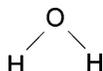
Preclinical development begins at some point after identification of an active compound and development continues through human clinical trials. The problems tackled during preclinical development continue during the clinical trials. During preclinical development, researchers evaluate candidates for such parameters as efficacy, side effects, pharmacokinetics (for example, absorption, distribution, metabolism, elimination and duration of action), and stability. Sometimes various pharmacokinetic properties and drug stability (for example, shelf life) can be modified by experimenting with changes to the form of the active compound or formulating it with specific

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23. See *infra* section 7:2 (compounds); section 7:4 (Method of Treatment); section 7:6 (nucleic acids); section 7:7 (Antibodies); see also *supra* section 1:3 for a discussion of the requirements for obtaining a patent.
  24. See *infra* section 8:1.8 (exemption from infringement related to FDA submission); see also chapter 11 (experimental use defense to infringement).

inactive ingredients known as excipients. Researchers must also usually develop methods for making large quantities of the active compound that are commercially practical and result in the desired level of purity. Preclinical development and clinical trials may also result in identification of new methods of treatment not identified during drug discovery and identification of therapies based on combining two active compounds in one formulation.

### [A] Form of the Active Compound

Active compounds, small molecules in particular, are generally claimed by specifying the compound's molecular formula (for example, H<sub>2</sub>O) and its structure (for example):



An active compound's properties, however, do not depend solely on its atomic composition. The form in which the compound is administered to a patient, such as its particle size, can also affect its properties.

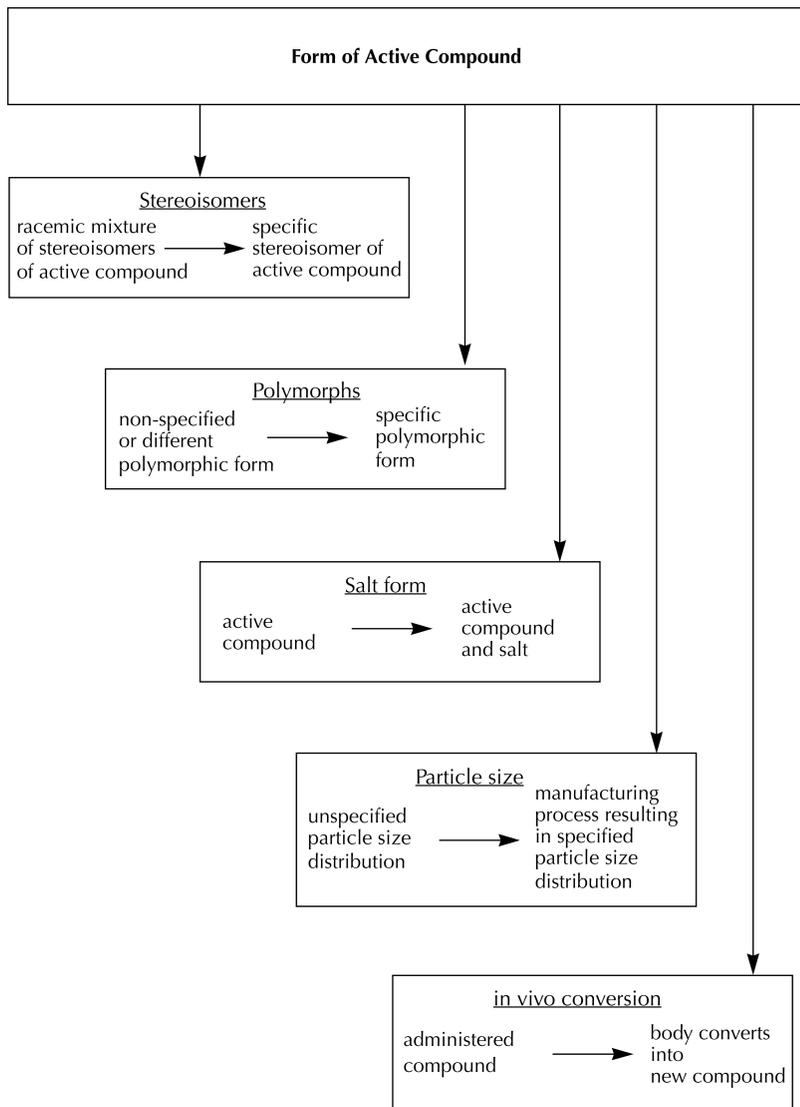
Active compounds can be placed into a variety of different forms to modify various properties such as pharmacokinetics and stability, as well as its biological properties such as efficacy and side effects. Modifying the forms of the active compound often produces unpredictable changes in its properties. Researchers, therefore, can potentially obtain patents on particular forms of the active compound even if the compound itself is known to the person of ordinary skill.

Figure 2-2 (below) illustrates the following ways in which the form of an active compound can be modified to change the compound's properties: preparing specific stereoisomers of the compound, preparing specific polymorphs of the compounds, putting the compound into a salt form, modifying the particle size of the compound, and selecting compounds that are converted in the body into other compounds with pharmaceutically desirable properties.<sup>25</sup>

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25. The foregoing ways in which the form of a compound can be modified are not exclusive. For example, a compound could be micronized to a desired particle size *and* put into a specified salt form if that results in an optimal mix of properties.

**Fig. 2-2**  
**Modifying Form of**  
**Active Compound**



**[A][1] Stereoisomers**

Certain compounds exist as stereoisomers, which means that the compounds are composed of the same constituent atoms but are arranged in space in different ways resulting in enantiomers (compounds that are mirror images of each other) and diastereomers (compounds with the same atoms, connected in the same way without being mirror images). Enantiomers and diastereomers are two types of stereoisomers. Such compounds can exist in mixtures of multiple isomeric forms or can be resolved into purer forms consisting of a single isomeric form with resulting differences in its properties.<sup>26</sup>

**[A][2] Polymorphs**

Compounds may also exist in different crystalline forms known as polymorphs. Polymorphs, like stereoisomers, are compounds that have the same chemical formula (type and quantity of atoms) but a different structural form. Polymorphism refers to the way in which the individual molecules stack upon each other to form crystals. Different polymorphic forms of a compound can impart different properties, serving as a basis for drug design and providing potential grounds for patent protection.<sup>27</sup>

**[A][3] Salt Forms**

Another way to modify the properties of a compound is to create a salt form of the compound. Different salt forms can affect various properties such as solubility, stability, and processability (ease of handling during the manufacturing process). A large number of potential salt forms exist, often with unpredictable properties, providing a basis for innovation and patentability.<sup>28</sup>

**[A][4] Particle Size**

Changing the particle size of an active compound can also change its properties. Micronizing particles of a compound, for example, increases a particle's surface area and thereby changes properties such as solubility and processability. This affords researchers yet another way to develop drug candidates and can provide a basis for obtaining patents.<sup>29</sup>

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26. See *infra* section 7:2.4.

27. See *infra* section 7:2.5.

28. See *infra* section 7:2.6.

29. See *infra* section 7:2.8.

**[A][5] In Vivo Conversion**

The body provides a final way to modify the form of an active compound. After administration of a drug, the body usually metabolizes (converts) the active compound into another compound as part of the body's natural process for ridding itself of foreign chemicals. The converted form of the administered compound, known as a metabolite, can have different properties from the original compound including retained or even enhanced pharmacological activity.<sup>30</sup>

**[B] Formulation**

Active compounds are usually mixed with inactive compounds to make a pharmaceutical formulation that permits administration in a convenient form. For many drugs, the most convenient form is a tablet or capsule. Other drugs, however, must be formulated in solution to permit injection for administration directly into the bloodstream or injection into a particular muscle, nerve, or other local site, or formulated as creams, pastes, inhalables, or other forms for a wide variety of reasons. The formulation design process must take into account the resulting composition's biological properties, as well as manufacturing issues and the end product's shelf life.

Formulation design presents a host of problems as well as opportunities to improve a drug's properties. For example, a drug with half life that is too short can sometimes be extended by developing an extended release formulation. Formulations are important to drug design and numerous patents have been awarded for pharmaceutical formulation. Many cases address issues concerning these patents.<sup>31</sup>

**[C] Manufacturing Process**

All active compounds are inevitably the end product of a manufacturing process. Most pharmaceuticals are made synthetically. Even natural extracts must be extracted.

The process for making the first small batch of test compound during drug discovery to identify potential drug candidates is often insufficient for large scale commercial production. New methods of manufacture, in a process known as "scale-up," must often be devised. The manufacturing design process can result in important innovations that should be protected by patents.<sup>32</sup> Furthermore, in some cases, the end product can only be described by the manner in which it

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30. See *infra* section 7:2.7, for a discussion of the variety of patent issues raised by *in vivo* conversion.

31. See *infra* section 7:3.

32. See *infra* section 7:5.

is made. These compounds are often patented by product-by-process claims that link the description of the compound to its manufacturing process.<sup>33</sup>

### **[D] Combination Therapies**

Researchers have found numerous instances where administration of two drugs to treat a single problem provides a superior therapy. Co-administration of two active compounds or administration of a single formulation that combines two active compounds into a single form such as a tablet can, in appropriate circumstances, be covered by a patent—even in cases where both active compounds were previously known.<sup>34</sup>

### **[E] Methods of Treatment**

During drug discovery researchers often have an idea about potential treatments available for compounds that show some activity in the initial assays. It is this hoped-for activity that has likely motivated the drug discovery effort in the first place. When such compounds are identified in the research phase of a drug R&D program, it is often prudent to file patent applications on the compounds and the methods of treatment identified by this research. Identification of new methods of treatment, however, does not end with the drug discovery or even with the entire preclinical phase. A better understanding of the compound's mechanism of action, further animal studies, or human clinical trials may yield new therapies for the drug candidates. Researchers and their patent attorneys must therefore be alert to opportunities for patenting new methods of treatment.<sup>35</sup>

## **§ 2:4.2 Clinical Trials**

If preclinical development results in identification of a drug candidate with sufficient promise, it must be subjected to rigorous testing in a series of human clinical trials. This process is highly regulated by the FDA. This process also affects the drug developer's intellectual property rights in a wide variety of ways. For example, the FDA approval process affects the commercial value of any patent rights associated with the drug therapy, and can affect the length of the patent term and provide non-patent based data exclusivity that prevents generics from relying on the innovator's clinical data for a certain period of time.

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33. See *infra* section 7:5.2.

34. See *infra* section 7:3.4[A][2].

35. See *infra* section 7:4.

**[A] The FDA Approval Process**

The FDA approval process is a topic unto itself deserving extensive treatment beyond the scope of this book. Nevertheless, it has become sufficiently entwined with patent law to merit discussion here.

**[A][1] Clinical Studies and Trials**

Human clinical trials must be preceded by pre-clinical studies described above to test safety and efficacy using available models.<sup>36</sup> FDA review generally begins with human clinical trials as illustrated in Fig. 2-3. Regulatory review can be broken up into a “testing” process and an “approval” process. Testing of human drug candidates, including biologics, is usually conducted pursuant to an Investigational New Drug Application (IND). The approval process begins when a New Drug Application (NDA), or in the case of a biologic, a Biologic License Application (BLA) contains enough information to permit FDA review.

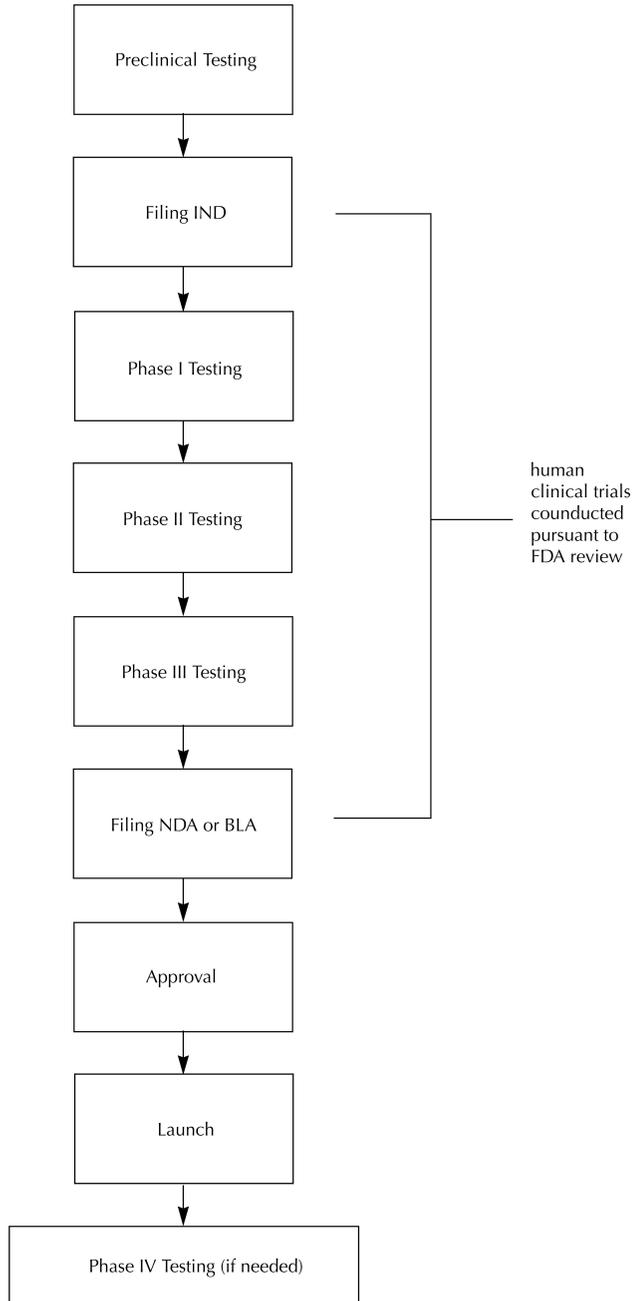
The pre-approval testing process is itself broken up into three phases of clinical trials. Phase I testing involves safety testing with a small number of healthy volunteers who take the drug candidate in increasing doses. Phase II involves testing larger groups for both safety and efficacy. Phase III involves the largest groups, often hundreds or thousands of patients, placed into randomized, controlled clinical trials resulting in the most definitive measurement of efficacy and safety. Depending on the circumstances, testing during human clinical trials presents a potential risk of public use of an invention that can result in loss of patent rights if patent applications were not filed within a year of the clinical trials.<sup>37</sup>

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36. See *infra* section 3:6.3, for a discussion on whether human clinical data is needed to demonstrate patentability.

37. See *infra* section 5:2.3[B][2][d].

**Fig. 2-3**  
**Phases of FDA Regulatory Process**



Post-approval testing, whether voluntary or required by the FDA, is known as Phase IV. Such testing can result in obtaining approvals for new indications but can also uncover new safety concerns that result in losing existing FDA approval. Clinical trials can also be conducted on children for pediatric indications and may result in an extension of existing patent or FDA based exclusivities known as pediatric exclusivity.<sup>38</sup>

### **[A][2] Patent Term Restoration for FDA Delay**

Congress provided a remedy to restore the effective loss of patent term due to delays in the regulatory approval process for pharmaceutical and other products, such as certain types of medical devices, subject to pre-market review.<sup>39</sup>

Accordingly, a patentee who complies with the appropriate regulations, which include filing an application for extension with the PTO (which the PTO in turn provides to the FDA), may be able to extend the term of an eligible patent with respect to a particular product.<sup>40</sup>

### **[B] The Hatch-Waxman Act: Generic Competition**

#### **[B][1] ANDA Litigation**

The Hatch-Waxman Act allows generic drug makers to file abbreviated new drug applications (ANDAs) without having to undertake the clinical trials described above that are required for approval of an innovator drug.<sup>41</sup> Presently, ANDAs can be filed for drugs approved pursuant to an NDA but not for biologic drugs approved pursuant to a BLA. An ANDA applicant only needs to show that the generic version and the previously approved innovator drug are “bioequivalent.”<sup>42</sup> To facilitate the research needed to file ANDAs, Congress immunized from patent infringement conduct that is reasonably related to drug development and the submission of applications for marketing approval.<sup>43</sup> On the other hand, Congress created a mechanism for innovators to litigate their patent infringement claims before FDA approval of the generic products, and barred the FDA from approving

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38. See *infra* section 8:3.5.

39. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669–70 (1990).

40. See *infra* section 8:4.

41. See *infra* section 8:1.1[C] (requirements for filing an ANDA).

42. See *infra* section 8:1.1[C][4] (bioequivalence).

43. Although the exemption from infringement for certain FDA related activity was intended to facilitate the filing of ANDAs, the exemption is not limited to ANDA filings. See *infra* section 8:1.8.

the generic products for up to thirty months when such a patent infringement suit is brought.<sup>44</sup>

### **[B][2] Data Exclusivity**

Congress gave certain rights to NDA holders, apart from patent rights, to compensate them for performing clinical studies and obtaining data to support the approval of new therapies. These grant rights, known as data exclusivity, generally take the form of various exclusivity periods, mostly independent of patent rights, during which the FDA may not approve competing products.

The following types of data exclusivity are available from the FDA for specific periods of time upon satisfaction of the appropriate conditions:

- New Chemical Entity (NCE) Exclusivity (five years data exclusivity)<sup>45</sup>
- Other Significant Changes (OSC) Exclusivity (three years data exclusivity)<sup>46</sup>
- Orphan Drug Exclusivity (seven years marketing exclusivity)<sup>47</sup>
- Pediatric Exclusivity (six-month extension to patent or data exclusivities)<sup>48</sup>

## **§ 2:5 Patent Protection for Pharmaceutical and Biotech Inventions**

The Patent Act permits patenting of many types of subject matter, so long as the patentability requirements are satisfied. An inventor may obtain a patent, according to the statute, for “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” upon satisfying the requirements for patentability.<sup>49</sup> Beyond this statutory definition of patentable subject matter, the statute does not generally define different types or categories of patents for any area of technology, including pharmaceuticals. Practitioners, however, find it useful to categorize pharmaceutical and biotech patents such as research tools, compounds, formulations, methods of treatment, methods of manufacture, nucleic acids, proteins, and antibodies. The categories are by no means exclusive. Many patent claims can easily fall within multiple categories. For example, a

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44. See *infra* section 8:1.4 (ANDA filing as an artificial act of infringement).

45. See *infra* section 8:3.2.

46. See *infra* section 8:3.3.

47. See *infra* section 8:3.4.

48. See *infra* section 8:3.5.

49. 35 U.S.C. § 101.

screening assay employing a nucleic acid sequence-based probe could be a research tool, medical diagnostic/method of treatment, and a nucleic acid sequence patent.

A discussion of research tool patents, including what these patents cover, how they can affect other parties' research efforts, the interface between research tool patents and the exemption from infringement for research directed towards generating data to submit for FDA approval, and efforts to conduct research efforts outside the United States to avoid the reach of research tool patents is provided in section 7:1. A discussion of chemical compound patents is provided in section 7:2. A discussion of pharmaceutical formulations and the issues unique to these types of patents, including an explanation of what formulation claims can cover, claim construction issues of certain terms that arise in pharmaceutical formulation patents, and examples of infringement and validity issues is provided in section 7:3. A discussion of method of treatment claims, including when conception of a method of treatment claim occurs, certain recurring claim construction issues such as when preambles (common to method of treatment claims) limit the scope of the claim, and proving infringement (often based on theories of indirect infringement) of method of treatment claims is provided in section 7:4. A discussion of pharmaceutical manufacturing, including manufacturing intermediates, product-by-process claims, and the patentability of process claims is provided in section 7:5. A discussion of nucleic acids and antibodies, and the growing body of case law and issues specific to these types of inventions is provided in sections 7:6 and 7:7.