chapter 1

Coordinating New Drug Application (NDA) and Patent Portfolio Strategy

I. Introduction

Innovators face evolving challenges when building their patent portfolios. Especially with the waning dominance of the “blockbuster,” no one-size-fits-all strategy can guide drug portfolio development through the complex maze of scientific, regulatory, and patent considerations. Because the innovator’s overall success is best advanced by a coordinated strategy covering all aspects of development, the objective of this chapter is to set a common foundation for the specific development phases and considerations addressed in the next few chapters.

The message, in short, is that strategic planning and coordination are necessary across all aspects and stages of pharmaceutical development. For example, there may be little (or no) commercial incentive to spend billions of dollars to develop a drug product for which there would be no period of exclusivity. Therefore, planning ahead to best ensure exclusivity, be it by patent or regulatory protection or ideally both, such as for an orphan drug indication, can be critical.

Consistent with the intended wide audience for this text, a team-based approach that incorporates input and vision across all areas of drug development, commercialization, and intellectual property (IP) protection will result in optimal coordination and strategic planning. Although continued uncertainty in the pharmaceutical landscape has made strategic planning

1. Mark J. Feldstein, PhD, Courtney B. Casp, PhD, Danielle A. Duszczyszyn, PhD, and Benjamin T. Hemmelgarn (summer associate) of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, D.C.
more difficult, financial constraints have made coordinated planning all the more important.

II. A Changing Landscape

A. The Impact of Portfolio Planning

Strategic portfolio planning is one of the most impactful steps toward product commercialization and should begin well before the Investigational New Drug (IND) Application and the New Drug Application (NDA) have been developed. Developing a strong IP portfolio directly adds value to a business by preventing others from practicing the claimed subject matter.2 Studies have also demonstrated a strong positive correlation between the size of the patent portfolio for a product and its sales.3

Patent protection for commercial drugs is all but essential. It protects the enormous pharmaceutical development time and costs, which can include more than ten years of research and cost billions of dollars.4 Only ten percent of drugs that enter clinical trials will be commercialized, so a significant portion of this development expense is associated with unsuccessful drug candidates.5 For large pharmaceutical companies, which typically investigate a large number of drug candidates, this expense can be particularly great. For smaller firms built around a single product, protection of that invention is all the more critical to the firm’s survival.

There are additional benefits attributed to a strategically planned patent portfolio. For example, the true value of patents may lie not in their individual worth but in their aggregate as a portfolio of related patents.6 In other words, “the whole is greater than the sum of its parts.”7 As a threshold matter, the cost to study the large portfolio of a potential competitor may serve as a barrier to entry, especially for smaller firms.8 Not surprisingly, a

6. Parchomovsky &Wagner, supra note 2, at 5-6.
7. Id. at 5.
large patent portfolio also can serve as a deterrent to litigation. Although generic competition in the Hatch-Waxman ANDA litigation context involves unique considerations, potential competitors understand that the broad scope of protection created by a well-planned portfolio increases the chances of claims covering a competitive product. Indeed, the likelihood of success of a portfolio holder winning an infringement case rises as the number of litigated patents increases.

A large and diverse patent portfolio also confers insurance against changes in patent law. Supreme Court cases like *Prometheus* and *Myriad* have undermined certain types of biotechnology methods and isolated gene claims. A well-planned portfolio protects against unforeseeable changes in patent law by protecting an invention with a wide variety of claim types and prosecution strategies.

Strategic patent portfolios also help leverage business negotiating power. Granting licenses to others can foster a wide variety of business transactions—from creating strategic alliances to preventing litigation through settlement or cross-licensing. Moreover, a large portfolio can stimulate outside interest in the company. For example, investors are more likely to invest when there is a broad, strategic patent portfolio rather than a few uncoordinated patents. Comprehensive portfolios are also an attractive asset to larger companies seeking to acquire a new product or technology.

**B. Looking Back at the Cliff**

Recent changes in the economic landscape have forced many companies to adjust their business strategies with respect to portfolio planning. In the past, pharmaceutical companies enjoyed great success with the blockbuster drug model, where drugs were intended to target diseases affecting large patient populations, like heart disease, in order to achieve high-volume

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10. Id. at 34.
11. Id. at 35 n.120.
12. Id. at 39-41.
sales of at least a billion dollars. The success of the blockbuster model was most evident in the early to mid-2000s. Indeed, in 2006, there were 52 blockbuster drugs that accounted for almost half of all U.S. drug sales.

Over the last few years, however, the number of drugs achieving $1 billion in sales annually has been decreasing. This decrease coincided with the passing of the “patent cliff,” the period between 2011 and 2016 when 20 blockbuster drugs faced patent expiry. This massive loss, combined with decreasing innovation, has made it clear that the blockbuster model of development is unsustainable and has forced pharmaceutical companies to reevaluate their business strategy.

A variety of factors further complicate the situation. For example, the cost of clinical trial testing has dramatically increased. It now costs an average of $34 million to take a drug from Phase I to Phase III and may cost as much as $100 million. The regulatory process governing Phase III trials is the biggest contributor to this increase. Over the past decade, the average trial length has grown, and the FDA has increased the stringency of its enrollment criteria and trial protocol requirements. Additionally, as these blockbuster drugs fall off the patent cliff, companies lose revenue streams and less money is available to be reinvested in new research and development. Further, in the wake of increased scrutiny after commercialized products were withdrawn from the market for safety concerns (think Vioxx®), the FDA has been more cautious in authorizing new drugs.

18. Id.
19. Id.
23. Id.
25. The loss of revenue from these drugs is significant: The 18 drugs that are going off-patent in 2017 represent $26.5 billion in annual sales. Eric Sagonowsky, Big Pharma Faces $26.5B in Losses This Year as Next Big Patent Cliff Looms, Analyst Says, FiercePharma (Apr. 21, 2017), http://www.fiercepharma.com/pharma/big-pharma-faces-26-5b-patent-loss-threats-year-analyst-says.
Lastly, the current political landscape has put pressure on pharmaceutical companies to provide more targeted therapies and lower prices.27 From the government side, for example, FDA Commissioner Dr. Scott Gottlieb listed increasing drug prices as a challenge his agency needs to address.28 Pressure also comes from the health care industry and general public, and pharmaceutical companies are aware that the old way of treating large populations with mass-market drugs is no longer acceptable.29 This has caused a transition into using diagnostics to provide outcome-based therapies (see infra Section IV.A).

The financial landscape for pharmaceutical and biotech companies has also changed. In 2012, for the first time in history, the U.S. drug market shrank.30 The billions of dollars lost to patent expiry is a primary factor. Pharmaceutical companies could lose another $26.5 billion in annual sales due to patent losses in 2017, which are much larger than losses in 2015 and 2016.31 The losses are not so surprising, as a name-brand drug can lose up to 80 percent of its worldwide market within three months of generic entry.32 For example, Lipitor’s sales plummeted after going off-patent, and its share of the U.S. market was only 18 percent in 2014.33 In response to these falling revenues, pharmaceutical companies have reduced research budgets, laid off employees, closed research centers, and sold off parts of their businesses.34 However, they have also managed to evolve to account for these changing conditions. Pharmaceutical companies have focused their research and development on “niche busters” and accompanying diagnostics, kept robust portfolios through acquisitions, and taken

28. Scott Gottlieb, Commissioner, Food & Drug Admin., FDA All Hands Meeting (May 15, 2017) (“For one thing, too many consumers are priced out of the medicines they need. Now, I know FDA doesn’t play a direct role in drug pricing. But we still need to be taking meaningful steps to get more low cost alternatives to the market, to increase competition, and to give consumers more options.”).
31. Sagonowsky, supra note 25.
32. MARTIN AUSTIN, BUSINESS DEVELOPMENT FOR THE BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRY 21 (2008).
advantage of regulatory exclusivities to extend the life of their protected
drugs. These evolving IP strategies, which will be discussed in detail, are
critical for any pharmaceutical company looking to compete in today’s
marketplace.

III. Strategic Portfolio Planning

A. Enacting a Team-Based Approach
As discussed earlier in this chapter, strategic portfolio planning is essen-
tial to enforce and defend IP rights, as well as enable collaboration and
further innovation. A team-based approach to portfolio planning and
management is most effective for both large and small companies. Field-
ing a team with multidisciplinary backgrounds provides balanced and
comprehensive insight, which helps inform decision making on whether
to file patent applications. This insight also provides for greater aware-
ness of unprotected areas that competitors may use to skirt one’s patent
portfolio or curtail future freedom to operate by patenting improvements,
add-ons, or alternatives to those offered in the patent portfolio. There are
many pitfalls of not coordinating technical, business, and IP strategies.
In the absence of collaboration, a company might pursue poor business
strategies based on the mistaken belief that they have sufficient IP pro-
tection, make product changes that adversely impact the company’s free-
dom to operate, or find that the product and patent claims are no longer
aligned.

An effective team should include technical experts who know the
current state of the art and can provide technical insight on novelty and
obviousness, marketing experts who can judge the commercial potential
of an invention, and an IP manager who consults with patent counsel and
management executives to periodically review and mine the patent port-
folio and pending applications to ensure they align with the company’s
objectives. But the teams should not only have individuals familiar with
the “big picture.” Equally important are team members who are “in the
weeds,” including contributors from drug discovery, drug formulation,
drug regulatory affairs, clinical pharmacokinetics, and licensing, who
bring specialized knowledge of the project to the table.35 These individuals
can provide helpful insight during prosecution, consider related technolo-
gies that may be covered by the claimed invention, and assess the market

potential of a technology. Rather than meeting just in the initial planning phase, the team should aim to meet regularly to ensure that the portfolio adequately reflects any changes in company goals and strategy, the current market, and the law.

IV. Building the Portfolio

Pharmaceutical business strategies have shifted and will continue to shift in response to the patent cliff and the reduced reliance on the blockbuster model. For established companies, many of these strategies begin with a fresh look at research and development along with reassessment of the existing IP portfolio. For newly formed companies, this provides an opportunity to develop an IP portfolio primed to maximize the potential for growth and development. For both established and nascent companies, however, strategic portfolio planning becomes more important and requires continued vigilance in order to successfully respond to the changing economic, financial, and political landscapes.

A. Research and Development

In the past, drug companies tended to avoid development of drugs targeted for smaller populations, as they were not likely to yield enough return on investment. The pharmaceutical industry is moving away from the blockbuster drug model that aims to provide a blanket treatment to a wide population and is instead focusing drug development on smaller patient populations. Thanks to advances in genetic sequencing and analysis, scientists have discovered many underlying genetic conditions that cause disease and affect drug efficacy. Drug developers are able to identify biomarkers linked to these genetic defects and direct research toward these biomarkers. Indeed, biomarker drugs account for an estimated 30 to 50 percent of drugs in current development. Research into biomarkers has given pharmaceutical companies reason to partner with the diagnostic

37. Id. at 42, 43.
40. Id. at 12.
industry in order to identify potential patients. A growing number of “companion diagnostic” tests have made it possible to predict whether an individual will respond to a therapeutic before beginning costly treatment. Careful portfolio planning is critical with personalized therapeutics—if the company producing the therapeutic also holds patent rights for the diagnostic test, there is an opportunity for an expanded financial benefit and better return on investment. Although diagnostic method patents are more difficult to obtain and defend in a post–Prometheus and Myriad world, they are not impossible under the right facts.

One area that biomarker research has profoundly affected is treatment of rare diseases. The U.S. Orphan Drug Act provides multiple benefits for development and commercialization of drugs to treat diseases affecting fewer than 200,000 patients. For example, companies are entitled to tax credits on clinical trial expenses, special grant funding from the FDA, and, perhaps most enticing, seven years of market exclusivity. Additionally, these drugs enjoy a faster track from Phase II testing to market, better odds for FDA approval, premium pricing given the smaller patient populations, and potentially lower development costs. Moreover, notwithstanding their smaller patient populations, orphan drugs have the potential for significant sales. Orphan indications also have the potential for patent protection, including as a new method of use for a previously known drug.

41. Id.
42. See Jimenez, supra note 29.
46. Id.
48. Id. (“Thanks to such high prices, almost a third of orphan drugs notch more than $1 billion in yearly sales, according to a sample reviewed by Thomson Reuters. The category has more than $50 billion in world-wide sales and has been rising more than 20% annually for the last several years.”); Gibson, supra note 38, at 13; Tribble, supra note 45 (“Orphan drugs now account for seven of the 10 top-selling drugs of any kind, ranked by annual sales. . . .”).
Biologics continue to receive attention as an alternative research and development strategy. Biologics are large-molecule drugs that are derived from living cells as opposed to chemical processes like traditional small-molecule drugs. Generally speaking, biologics are more difficult to make than small-molecule drugs and may be difficult to precisely reverse engineer, making copying more difficult for generic competitors. Biologics offer other unique advantages, such as 12 years of FDA data exclusivity in contrast to the 3 to 5 years normally allotted for small-molecule drugs. As the average breakeven point on research and development investment requires 12.9 to 16.2 years of exclusivity, the automatic 12 years of biologic exclusivity is particularly significant. Perhaps this is why biologics are projected to represent more than 30 percent of total pharmaceutical sales over the next decade.

Patent protection for biologics, however, is often perceived to be weaker than for small-molecule drugs. This is because, unlike with small-molecule drugs, broad claims to structurally similar drugs are often not granted due to the unpredictable biologic side effects caused by even small structural changes to the biologic. Thus, there is an even greater premium on portfolio planning and protection strategies tailored to the specific case. Trade secret protection of biologics may also be a potentially valuable intellectual property portfolio asset.

B. Cost/Benefit of Filing

Portfolio strategy requires a balance of short-term pressures with long-term planning. Although there are risk assessment models that which can be utilized to determine the probability of success of products in different

49. How to Survive the Patent Cliff, supra note 43.
50. Id.
51. Id.; 42 U.S.C. 262(k)(7).
52. How to Survive the Patent Cliff, supra note 43.
54. Id.; see Dan Lonkevich, Biologics Makers Are Learning Narrower Claims May Help Them Win Patent Disputes, PAT. INV. (Apr. 15, 2016), https://thepatentinvestor.com/2016/04/biologics-makers-are-learning-narrower-claims-may-help-them-patent-disputes/; In re Wallach, 378 F.3d 1330, 1335 (Fed. Cir. 2004) (affirming rejection of patent claim to 30 kDa (roughly 250 amino acids) protein where only 10 amino acids were specified because there was “no evidence that there is any known or disclosed correlation between the combination of a partial structure of a protein, the protein’s biological activity, and the protein’s molecular weight, on the one hand, and the structure of the DNA encoding the protein on the other”).
stages of development, patent filing decisions must be made early in a drug’s developmental timeline to avoid risking any loss of rights.

On the one hand, patent prosecution and maintenance costs can be expensive and can be especially burdensome for a company that is pre-revenue. Costs can vary dramatically depending on the complexity of the invention, the number of claims, and the country in which the application is filed. Moreover, once the patent has issued, the patentee must pay maintenance fees on both U.S. and foreign patents.

On the other hand, prosecution and maintenance costs can usually be more than justified for a successful product. Just one extra day of patent protection for a billion dollar drug amounts to nearly $3 million in additional revenues. The problem, however, is that only a small fraction of candidates become commercial products. As a result, the majority of pharmaceutical patents do not cover commercial products. An internal strategy, aligned with business goals and commercial expectations, becomes essential to focus limited IP budgets on maximizing protection and minimizing expenses.

C. Timing of Filing

In addition to deciding where and what to file, timing is an important strategic tool, as discussed in more detail elsewhere in this book. Early in the drug discovery process, it is difficult, if not impossible, to ascertain which drugs may end up being commercialized. Naturally, companies may hesitate to file applications on drug candidates without a better indication of which compound may be successful. Moreover, because the lifespan of a U.S. patent is 20 years from filing, there may also be temptation to file a patent later in the drug development process, especially because it takes 3 to 6 years to obtain a patent and 10 to 12 years for a drug to reach the market.
market. But delayed filing increases the probability of encountering prior art that will challenge patent validity.

Rather than delaying patent filings, it may be appropriate to consider other means for controlling expenses and extending protection for the actual commercial product. For example, Patent Cooperation Treaty (PCT) applications may extend the time from filing until prosecution, thereby deferring some prosecution costs while, at the same time, securing an early priority date. Subject to the many requirements for patentability, applications directed to improvements can be filed later. Or, if the development is unsuccessful while prosecution has been deferred, the patent filing can be abandoned to avoid unnecessary costs.

As for maintaining exclusivity, various regulatory extensions are available. In the United States, for instance, pursuant to 21 U.S.C. § 360cc and 21 C.F.R. § 314.108, respectively, an orphan drug receives seven years of market exclusivity and a new chemical entity (NCE) receives five years of market exclusivity. Regulatory exclusivities are discussed further in Chapter 8.

While filing early to ensure coverage and to discourage competition is often the best practice to obtain an early priority date and allow time for prosecution to be completed before commercial launch, there may be times when this is not possible. When a patent application cannot be filed early, it may be important to accelerate prosecution of a later filed application. For example, in the Hatch-Waxman context, a 30-month stay of generic approval may not be available if the innovator’s patent is listed after the generic’s ANDA is filed. Fortunately, the USPTO (U.S. Patent and Trademark Office) has introduced a number of new processes that help to accelerate the patent prosecution process.

First, the “accelerated examination” program promises that final decisions on patentability will be rendered within 12 months of filing if the applicant provides certain additional information and fees. Second, the USPTO has a “Track One” prioritized examination program. As with accelerated examination, Track One applicants will receive final decisions within 12 months, and possibly as quickly as six months. The fees for

Track One are significantly higher than accelerated examination. However, unlike with accelerated examination, Fast Track does not require an examination support document detailing how each claim is patentable over the prior art.68 Third, the USPTO extended its Full First Action Interview Pilot Program, such that it continues to be open for all art areas.69 This program allows applicants to interview with the patent examiner assigned to their application before a first office action on the merits issues in a utility patent application.70 During this interview, written description and patentability issues can be resolved, thereby advancing the patent prosecution process. Although no formal guarantee of accelerated final disposition exists, the first action allowance rate and overall allowance rate are much higher than regular applications at 30 percent and 90 percent, respectively.71 Fourth, the USPTO has launched pilot programs aimed at simplifying the Patent Prosecution Highway (PPH) process.72 This international program relies on prosecution in a corresponding foreign application filed in a participating country to speed up examination.73 PPH offers shortened wait time before examination74 and high allowance rates.75 These accelerated processes offer the possibility for increased certainty before investing in further product development.

D. Acquisitions
As many blockbuster drugs go off-patent and the number of new drugs in the pipeline decreases, many pharmaceutical companies are pursuing

70. Id.
71. Laub, supra note 68.
73. Id. When an applicant receives a final ruling from a patent office participating in the PPH that at least one claim is allowed, the applicant may request fast track examination of any corresponding claim(s) in a corresponding patent application that is pending in a second patent office (e.g., USPTO) also participating in the PPH. This allows applicants to reach final disposition of a patent application more quickly and efficiently than standard examination processing.
74. PPH applications are typically examined within two to three months of a granted PPH request. Laub, supra note 68.
75. PPH applications have an allowance rate of over 90 percent compared with 60 percent for non-PPH applications. Id.
products either by acquisition or by in-licensing technology.\textsuperscript{76} Although some of the risk involved in research and development can be bypassed by acquiring compounds that have been through preliminary clinical testing, more assets are being acquired in earlier stages of development.\textsuperscript{77} This is probably due to some combination of increase in high-quality early candidates and decrease in low-risk late-stage candidates.\textsuperscript{78} Nonetheless, the number of acquisitions continues to rise,\textsuperscript{79} and some transactions are particularly large.\textsuperscript{80}

By contrast, in-licensed compounds might be more expensive in the short term and deliver less profit in the long term, but the reduced development risk can make them a sound business investment.\textsuperscript{81} For instance, in contrast to the extremely long odds for an untested drug product, a drug in Phase III testing has an estimated 58 percent chance of developing into a commercially viable drug product.\textsuperscript{82} Understandably, licensing costs increase with each stage in development the drug reaches.\textsuperscript{83} It is unlikely, however, that such products would be acquired absent a strong patent portfolio.

**E. Reassessing Existing Portfolios**

Likewise, reevaluating existing patent portfolios for repurposed drugs with new indications, formulations, or novel manufacturing techniques has also proven to be a successful business strategy for pharmaceutical companies.\textsuperscript{84} One caveat of this strategy is that it requires careful analysis of the existing patent portfolio for the repurposed drug, especially when the

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\textsuperscript{76} In-licensing is the practice of obtaining rights to third-party technology by license, as opposed to developing that technology internally. Song & Han, supra note 8, at 2–3; Knowles, supra note 61, at 29.


\textsuperscript{78} Id.

\textsuperscript{79} Id.


\textsuperscript{82} Id.; BIO INDUSTRY ANALYSIS, supra note 5, at 7.

\textsuperscript{83} Knowles, supra note 61, at 29.

new chemical entity (NCE)\textsuperscript{85} was developed by another company, in order to evaluate whether the new use is covered by existing patents or whether additional protection is available.\textsuperscript{86} Used successfully, this strategy can extract additional value from a company’s existing or underutilized intellectual property assets or create new opportunities for other companies.\textsuperscript{87}

\section*{V. Managing the Portfolio}

Safeguarding long-term exclusivity or market share requires an active strategy that employs both offensive and defensive approaches. Periodically reevaluating potential weaknesses throughout the portfolio will help to strengthen the patents and increase the breadth of protection. This ongoing process requires constant review of the market and literature, internal research and development, and monitoring competitors to identify potential patentable and commercially significant improvements.

One offensive strategy involves obtaining new patents on improvements, such as new dosage forms or compositions, which can provide additional protection. Another strategy involves amending pending claims to cover products within the scope of the inventive concept that competitors might develop in the future. Also, publication in the scientific literature can be used to prevent competitors from obtaining blocking patents around the same technology. This can be especially important as small companies and treating physicians have been known to file for patent protection for methods of using another company’s product and then later sue that company for infringement.\textsuperscript{88}

As discussed earlier, while quantity itself may confer some level of deterrence, it is crucial to focus on the quality of the basic patents that form the cornerstones of the portfolio. Though quick action is initially tempting, long-term interests may best be served by steering clear of short-term monetary savings gained by cutting corners on one’s own portfolio. In other words, investing time, expertise, and effort into planning, drafting, and prosecuting initial cornerstone patent filings is essential as these will ultimately form the strong foundation for a constantly growing and evolving portfolio.


\textsuperscript{86} Id.

\textsuperscript{87} Id.

\textsuperscript{88} See 35 U.S.C. § 102(a)(1) (“A person shall be entitled to a patent unless the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.”).
VI. Utilizing the Portfolio

Companies can also stand to benefit from reevaluating their current portfolios with an eye for underutilized IP. While IP monetization, including out-licensing patents to other pharmaceutical or biotechnology firms, has been historically uncommon among pharmaceutical companies, the potential is significant. As discussed earlier, for every pharmaceutical patent covering a commercial product, there are nine additional patents in a company’s patent portfolio that are not being used. In addition to increased utilization of one’s own patents, licensing deals may be written to allow access to reciprocal technology from the licensee.  

There are a number of potential strategies aimed at increasing the performance of unused IP. One involves using monetization companies that create and maintain a public database of available licensing technologies in order to advertise available IP. A second option would be to encourage the formation of smaller spin-off companies that focus on developing discrete technology areas. In either case, it may be possible or preferable to limit the field of use to be noncompetitive, such as for veterinary use or distinct indications.  

Patent pools are another patent monetizing strategy used successfully in other industries, especially the IT industry, as a mechanism to facilitate licensing. In the past, patent pools in the biotech and pharmaceutical industry were charitable entities that provided public access to patents

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89. See 35 U.S.C. § 102(a)(1) (“A person shall be entitled to a patent unless the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.”).
90. Song & Han, supra note 8, at 10.
91. Knowles, supra note 61, at 33.
92. Id. at 34–35.
93. Id. at 35-36.
related to under-researched medical disorders. The creation of commercial patent pools, however, might be another mechanism for pharmaceutical and biotechnology firms to facilitate the monetization of underutilized IP. Commercial patent pools might prove to be particularly advantageous in the biotechnology industry as a means to facilitate licensing of diagnostics and research tools.

One such pool, MPEG LA’s Librassay, was designed to address licensing issues in diagnostics and personalized medicine. At last count, this pool contains over 400 patents and facilitates royalty-bearing and royalty-free licensing for a wide variety of technologies and disease states. Another pharmaceutical patent pool is the Medicines Patent Pool, which has a pool of patents specifically directed to HIV, viral hepatitis C, and tuberculosis treatments. These pharmaceutical pools have the potential to provide greater access to beneficial IP that might otherwise go unused, while still allowing patentees to recoup some of their financial investment. If the income generated by participating in these pools is sufficient, these patent pools will attract others to submit their patents, which should simultaneously spur innovation and provide an additional income stream to cash-strapped firms.

VII. Conclusion

All strategic business planning—from research and development to commercialization—relies integrally on the strength of the portfolio protecting the product. Achieving a comprehensive and diverse patent portfolio is best achieved by a coordinated strategy specific to the product that takes into account all aspects of drug development, regulatory approval, and competition.

A more in-depth explanation of the stages of development of a commercial pharmaceutical product, from preclinical research through pre-litigation investigation, follows in Chapters 2–5. Through all of these chapters, portfolio planning and management should be an ongoing focus in order to ensure the most comprehensive coverage for any potential commercial product. These next few chapters will also detail the importance of proactive portfolio planning throughout development and commercialization. This strategy provides the best chance for a return on investment, making it an essential strategy for pharmaceutical and biotech firms of all sizes.

94. Id. at 35.
95. Id. at 36.
96. Id. at 37.