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Improvements for Handling Improvement Clauses in IP Licenses: An Analytical Framework

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In 1985, Amgen was a fledgling biotechnology company just four years old.1 Faced with a dilemma common to many start-up biotechnology companies, the company had two promising drugs, Epogen® and Neupogen®, but was cash strapped and did not have nearly enough money to develop the two products.2 To make its financial situation worse, Amgen was burdened with the prospect of a costly patent battle with Genetics Institute over the commercialization of its Epogen product, a promising new recombinant protein product called erythropoietin alfa (EPO) useful for treating various forms of anemia.3 As a consequence of these pressures, Amgen did what many biotechnology companies faced with such prospects do: it forged a deal with Ortho Pharmaceutical, a subsidiary of Johnson & Johnson.4 In return for a much needed cash infusion of $10 million dollars, Amgen granted Ortho exclusive worldwide rights to sell EPO while retaining its own rights to sell EPO for the kidney dialysis market in the United States.5 Following the deal, Ortho launched its EPO...
product under the trademark Procrit® in the United States for the larger non-dialysis market and Amgen launched its Epogen product for the dialysis market. At the time, the deal was a lifesaver for Amgen, but it also deprived the company of approximately two-thirds of the market for its Epogen product.

Fast forward to 1998. Amgen’s Epogen product, used to treat anemia associated with chronic renal kidney dialysis was its lead product with 1997 sales of $1.16 billion. However, as a result of the 1985 agreement, Amgen was deprived of the more lucrative non-dialysis market. Thus, in order to capture that market, Amgen developed a new improved version of EPO, a hyperglycosylated analog of EPO known as NESP, which Amgen claimed had a threefold longer half life than the original EPO product, giving the analog the potential advantage of less frequent dosing. Amgen then executed a legal strategy in which it claimed that NESP was not covered by the 1985 license agreement with Ortho. If such argument were successful, Amgen would have access to the lucrative worldwide non-dialysis market, estimated to be at least $1.35 billion in 1998.

Ortho disputed Amgen’s interpretation of the 1985 agreement, contending that NESP was an improvement covered by the agreement to which it had exclusive rights outside the dialysis market. The case went to arbitration, and, in 1999, an arbitration panel in Chicago ruled that Amgen had exclusive rights to NESP and that the new analog was not an improvement covered by the 1985 license agreement to

http://www.sec.gov/Archives/edgar/data/318154/0000318154-98-000003.txt (explaining that license granted Ortho exclusive rights to non-dialysis market in United States and to all treatments worldwide except in Japan and the People’s Republic of China where Kirin Breweries retained such rights).

6. Amgen Case Study, supra note 1.
7. Id.
8. Amgen 10-K, supra note 5, at 35.
10. NESP is an acronym for novel erythropoiesis-stimulating protein. Id.
11. Id.
12. Id.
13. Id.
14. Id.
Ortho. In addition to giving Amgen access to the lucrative market for EPO, the decision sent Amgen’s stock price surging 23%.

The Amgen/Ortho case study highlights the critical importance of considering improvement clauses in licenses of patents and copyrighted works. Absent a more refined improvement clause, the two companies were left to battle whether the original licensing agreement governed NESP. As this case illustrates, although the focus of the particular agreement may be for the existing work, as time passes, the work’s improvements may prove the most important to both the licensee and licensor.

This article addresses the current legal issues surrounding improvements in copyright and patent law, pointing out why improvement clauses can be critical, and providing an analytical framework for determining how to handle improvement clauses in licensing agreements. As considered here, emphasis is given to improvements made by a licensor; however, this general discussion is equally relevant to improvements made by a licensee, which are typically governed by grantback clauses. In Part I, the article provides some legal background on copyrightable and patentable improvements and discusses the present use of improvement clauses. In Part II, the article turns to case law and other sources to illustrate the importance of improvement clauses. Part III focuses on the challenges that arise when negotiating improvement clauses. In Part IV, the article offers an analytical framework and practical suggestions for dealing with improvements, including how improvement clauses should be analyzed and structured. Part V summarizes the article’s analysis of improvement clauses. Finally, the article concludes with an appendix containing examples of various clauses that can be used to address improvements in licensing agreements.

I. BACKGROUND ON IMPROVEMENT CLAUSES

When considering improvements in the context of intellectual property, it is essential to understand the nuances of copyright and patent law. While both branches of intellectual property law contain statutory provisions addressing improvements, the rights to original creators and inventors differ between the two. A review of the legal doctrines surrounding such improvements will provide a basis for a

15. Fürst, supra note 9.
16. Id.
better understanding of the operation of improvement clauses in the licensing context.

Under copyright law, a creator enjoys an exclusive right to "prepare derivative works based on the copyrighted work." That is, he may change or improve his creation in a non-trivial way and secure a copyright to that improved work. In addition, the original copyright holder has the sole right to give permission and/or to grant a license to another to make a derivative work on which a copyright can adhere. Without such permission by the original creator, any improvement to the copyrighted work by another party is an infringement of the original holder's copyright. Not only must the would-be improver seek permission from the original copyright holder, but she must also overcome a higher originality requirement for the derivative work than did the original creator for his work. As a result of these statutory provisions and common law doctrines, the treatment of improvements is generally favorable to the original copyright holder. In relation to a licensing agreement, the two parties must discuss whether the agreement extends to derivatives that the original copyright holder might make and whether the original copyright holder will give permission to the potential improver to make such derivative works.

In contrast to copyright law, patent law does not vest in the original patent holder any right to improvements or derivative inventions. Instead, a patent serves as a right to exclude others from the patented invention. Notwithstanding that right, a new and separate patent can issue for an improvement to an invention. Consequently, a patent holder may find herself frustrated if another successfully designs around or substantially improves her original patent and then secures a new patent on the improvement. In many

18. Of course, the derivative work's copyright only extends to the newly contributed material, not to the original work. See 17 U.S.C. § 103(b) (2000).
19. See, e.g., Pickett v. Prince, 207 F.3d 402, 406 (7th Cir. 2000) (stating that Plaintiff's guitar, which was in the shape of the symbol of rock artist Prince, was a violation of copyright since Plaintiff had not received permission or license from Prince to use the said symbol).
20. See L. Batlin & Son, Inc. v. Snyder, 536 F.2d 486, 492 (2d Cir. 1976) (en banc), cert. denied, 429 U.S. 857 (1976) (holding that a copyright should not be granted to a plastic version of a formerly cast-iron Uncle Sam bank because the change in material was only trivially different than the original and required no skill or creativity).
cases, the improvement patent is "blocked" by the original patent holder, i.e., such improvement cannot be exercised without a license from the original patent holder whose technology has been incorporated into the improved patent. Similarly, the original patent holder is blocked by the improved patent from practicing the improvement. Consequently, one or both patent holders need a license from the other in order to practice his/her invention. Because of the possibility of mutual patent blocking, both parties in a patent licensing agreement should discuss whether improvements are to be governed by the negotiated agreement. Even when the licensee simply wishes to have access to improvements that the licensor might make during the term of the agreement, improvements should be addressed within the terms of the original licensing agreement.

II. WHY IMPROVEMENT CLAUSES MATTER

The decision to include a provision for improvements in a licensing agreement depends upon the overall objectives of the contracting partners. Generally improvement clauses can be an essential element of a license agreement. A well-crafted clause can provide clarity so as to avoid future disputes and can provide the benefit of the bargain in a licensing agreement. Unfortunately, such clauses are often overlooked or receive gloss treatment. The danger in superficial treatment of an improvements clause can be illustrated by considering three situations in which improvements have great importance to both a licensee and licensor. The first situation arises in litigation, where licensing parties spar over the terms and definitions of a technology improvement. As many litigants have found, without better direction from the licensing agreements themselves, the courts are left to a fact-intensive inquiry as to what the parties intended to include in an umbrella term like "improvements." The second situation arises when the licensee and licensor are dealing in a technology that straddles both copyright and patent law, e.g., source code. In these situations, both the licensor and the licensee must be watchful that each understands how improvements and derivatives of the original licensed work will be handled. The final situation that illustrates the importance of improvement clauses concerns policy decisions about the future direction of copyright and patent law.

23. The concept of "blocking patents" is common in the biotechnology industry and has been widely discussed by Robert Merges. See, e.g., ROBERT PATRICK MERGES, PATENT LAW AND POLICY 698–701 (2d ed. 1992).
A. Cases Where Improvement Clauses Matter

One of the more agonized interpretations of "improvements" can be found in Deering Milliken Research Corp. v. Leesona Corp. There, the dispute revolved around the scope of "improvements" as suggested by the licensing agreement whereby Deering Milliken gave Leesona a royalty-free license to manufacture and sell a particular apparatus used in manufacturing elasticized yarn. The license included a provision which stated that "[a]ny improvements made on the apparatus or process which is the subject matter of this agreement... shall become the property of [Deering]." In time, Leesona created a device, which improved the manufactured yarn that Deering considered an improvement on its own apparatus and thus sued. Relying on technical distinctions, both the trial and the appellate court held that the new apparatus was not an "improvement" on the first. Appreciating that their technical interpretation was murky, the Second Circuit emphasized that if Deering had meant for the improvements provision to cover an improvement in yarn, instead of simply covering improvements in the mechanisms to make such yarn, then Deering should have used "clear, deliberate, and appropriate language" in its agreement with Leesona. The moral is that clear language is critical if a licensor does not want a court to create its own definition of what constitutes an improvement.

Four decades after the Deering Milliken case, courts still struggle with the definition of improvements, suggesting that drafters of licensing agreements have not improved their own ability to craft improvement clauses. This conclusion is supported by the case of U.S. Valves, Inc. v. Dray. There, the Federal Circuit Court reviewed the lower court's finding that Robert Dray breached his license with U.S. Valves and determined whether the court's damage award was appropriate. In the original licensing agreement between Dray and U.S. Valves, Dray licensed his patented product and all future

24. 315 F.2d 475 (2d Cir. 1963).
25. Id. at 476.
26. Id. This is an example of a grantback provision in a licensing agreement whereby the improvements developed by the licensee, Leesona, would be granted back to the licensor, Deering.
27. Id.
28. Id. at 477.
29. Id. at 478.
30. 212 F.3d 1368 (Fed. Cir. 2000).
31. Id. at 1371.
improvements of the product to U.S. Valves in return for royalties on sales of the product. As often happens, eventually the relationship between Dray and U.S. Valves soured, at which time Dray dissociated himself from the company but did not terminate the license. Instead, Dray began selling the licensed product himself shortly thereafter. At that time, he also began producing and selling another valve which he called the "sliding ring" valve that essentially served the same purpose as the original licensed product. Although the appellate court agreed that Dray had breached the licensing agreement with U.S. Valves, it was unable to affirm the damages award due to the broad language of the improvements provision. At issue was whether the "sliding ring" valve was an improvement to the licensed product; if it was, then Dray would be liable for damages to U.S. Valves for the sale of such valves. Lacking direction from the licensing agreement, the Federal Circuit remanded the case for proper analysis by the lower court.

In addition to demonstrating the difficulty of drafting clear improvement clauses, recent cases also illustrate the importance of considering how improvement clauses interrelate with other provisions in a licensing agreement. As with every element of a licensing agreement, it is critical to understand the relationship between an improvements provision and other terms, e.g., scope, obligations, rights, etc., in the agreement. A recent case that illustrates this point is Speedplay, Inc. v. Bebop, Inc. There, two competing manufacturers of clip-less bicycle pedal systems were engaged in a patent infringement suit with regard to their respective pedal systems. In its response to Speedplay’s infringement claim, Bebop argued that Speedplay lacked standing to bring suit. Bebop reasoned that only the original inventor of the Speedplay pedal system had such standing because, in the license with the original inventor,

32. Id. at 1370 (stating that the agreement included a provision whereby "all future improvements, modifications or enhancements of the Licensed Product made by [Dray] shall be Licensed and . . . made available to [U.S. Valves]").
33. Id.
34. Id.
35. Id.
37. Id. at 1375.
38. Id.
39. Id.
40. 211 F.3d 1245 (Fed. Cir. 2000).
41. Id. at 1249.
42. Id.
Speedplay agreed to assign back to him any improvements that it made to the pedal during the term of the license back to the owner. The court disagreed with Bebop’s analysis and said that while the original inventor had a reversionary interest in improvements made by Speedplay, the inventor's overall right with respect to the improvements was limited by other provisions in the agreement. According to the court, while the “Improvements clause thus serves to protect... reversionary interest in any improvements, [it does not] limit [the licensee’s] proprietary interests in improvements...”

B. Importance of Improvement Clauses in Source Code Licensing

These three cases help show the importance of improvement clauses and point out the risks when the clauses are either not well written or even carefully considered before drafting a licensing agreement. Notwithstanding such litigation risks, there is an additional situation highlighting the importance of improvement clauses. It concerns unauthorized derivative source code, a type of work not addressed by the presented cases.

As at least one commentator warns, source code licensors and licensees should pay particular attention to the scope and definition of rights for unauthorized source code. Absent specific language whereby any improvements to or derivatives of a copyrighted work are assigned back to the original creator, a licensor of source code may be dismayed to learn that he cannot prevent a creator of unauthorized derivative source code from using, copying, etc. the improved work. This is possible in certain situations such as when: the original source code was specifically not copyrighted as is the case in open source code; the improvement doesn’t fit under the statutory provision for a derivative work; or the improvement is

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43. Id. at 1252 (relying on language in the license agreement, which was between Speedplay and the original inventor, that stated any improvements were to be “assign[ed] to [original inventor/licensor], as tenants in common, all right, title and interest in and to the Improvements”).
44. Id.
45. Id.
47. Id. at 8.
48. Id. at 2.
49. Id. at 8.
Likewise, a licensee should understand that if she makes an improvement to the copyrighted work that is considered an unauthorized derivative of the original, then she might be estopped from using it. Thus, both the licensor and the licensee should carefully consider the terms of improvements and derivatives in licensing agreements for copyrighted works.

C. Policy Decisions and the Importance of Improvement Clauses

The final situation that illustrates the importance of improvement clauses is found in the policy debate concerning the future of copyright and patent law. Prof. Mark Lemley has assembled convincing arguments for why he believes the treatment of improvements in copyright and patent law should be aligned. His general thesis is that the copyright doctrine should support a concept analogous to the "blocking patent" doctrine.

Professor Lemley predicates his thesis with a lengthy discussion of the benefits of improvements to copyrighted and patented works and of the existing costs and inefficiencies surrounding licensing such improvements. As he notes, "[i]ntellectual property is fundamentally about incentives to invent and create." Thus, the "rules governing improvements are important in understanding the extent to which protection for first-generation innovation will impede improvement in subsequent generations."

Assuming that radical change to the structure of the copyright and patent law is not forthcoming, Professor Lemley's thesis may not be immediately relevant to current practitioners. Nevertheless, his discussion of the inherent costs of licensing and his caution that improvements, more generally, should be carefully understood is relevant. For example, drafters should strive to minimize the costs of licensing by structuring improvement clauses that provide appropriate incentives to create improvements and encourage unfettered improvement, but that also protect the respective interests of both the licensee and licensor.

50. Id.
51. Id.
53. Id. at 992.
54. See id. at 993-1000 (discussing the economics of invention and improvement).
55. Id. at 993.
56. Id. at 998.
III. CHALLENGES IN NEGOTIATING IMPROVEMENT CLAUSES

As previously noted by Professor Lemley, significant costs and challenges can arise when negotiating license agreements. In addition to the inherent tension between licensor and licensee, there are other complications that can serve as roadblocks to a successful negotiation of improvement clauses.

Not surprisingly, even though two parties to a licensing agreement are pursuing a common goal, they often have different concerns and objectives in achieving that goal. For example, a licensor who invented a particular technology and plans to continue development on that technology may not desire his improvements to automatically be subsumed within his original licensing agreement with the licensee. This is often a challenge to licensees working with universities or other research facilities. Similarly, if a licensee has higher expectations for continued research and development of a licensed product, she may not accept an agreement whereby all improvements revert back to the licensor. Naturally, both parties will seek to protect their interests while also establishing a productive and trusting relationship.

In many cases, the logical source for improvements is the licensor because he developed the initial technology and naturally has the expertise and know-how to make improvements. In such an event, a licensee who obtains rights to only a narrowly defined product is likely to feel cheated when the licensor makes an improvement that is not included in the license and renders the licensed product obsolete. In contrast, the licensor frequently desires to make improvements and receive additional compensation on further developments, often including the freedom to seek new partners, reserving for himself the right to market improvements. In any event, proper consideration of improvement rights is imperative in the course of negotiating and drafting the applicable agreement.

57. See generally supra note 54.
59. Id. at 283 (noting that improvement clauses should be included in a "basic" license agreement for biotechnology-related products).
60. The importance of building trust in a licensing relationship is particularly acute when dealing with improvements because the identification and definition of improvements can be difficult to make. See JAY DRATLER, JR., LICENSING OF INTELLECTUAL PROPERTY § 1.04[7] (2003).
Defining improvements and negotiating the rights thereto can present one of the most challenging aspects of the negotiation and drafting of licensing and acquisition agreements. Patent lawyers are trained to draft patent specifications and claims with an eye to covering future improvements; therefore, the patent rights, if any, are often helpful in defining improvements. However, many different considerations and limitations concerning patentability arise when drafting patents than those that arise in the contractual context. Moreover, different legal considerations exist in the context of improvements in a license to a patent as compared with a license to a copyright, trademark, or trade secret. For all these reasons, each case must be analyzed on its own terms and careful consideration must be given to the context of the agreement.

In addition to possibly conflicting objectives when negotiating improvement clauses, a licensor and licensee must also be attentive to not run afoul of patent misuse or antitrust doctrine. Although the Supreme Court has long held that a grantback of intellectual property rights is not patent misuse per se, some courts have found misuse when the “scope of the grantback is broader than the scope of the licensed patents.” Further, if the licensing agreement falls under European Union jurisdiction, then the parties must ensure that the improvements grantback is not exclusive with respect to severable improvements and that the licensor grants a reciprocal license to the licensee/grantbackee.

IV. STRUCTURED THINKING ABOUT IMPROVEMENT CLAUSES

As illustrated by the preceding discussion, improvement clauses do matter but can be difficult to negotiate and define. Regrettably, current model clauses provide little direction to practitioners who appreciate that their licensing agreements need to include such clauses, but who do not know the best way to think about them. What practitioners need is a comprehensive framework by which they can consider improvement clauses.

A possible solution to this dilemma is a structured, yet simple, analysis for improvement clauses. Although no strict rule for drafting and negotiating improvement clauses can be given, the following framework can be used as a mental checklist for thinking about the issue. In this context, emphasis has been given to the rights to improvements made by the licensor regarding a patented technology. However, equal consideration should be given to the circumstances concerning the grantback of rights to improvements made by a licensee. Further, the framework has usefulness to copyright holders and licensees who need to decide whether derivative works are to be included in the initial license.

A. The Decision Tree

The proposed analytical framework for considering the issue of product improvements made by the licensor/grantor is presented in Figure 1. This general “decision tree” is relevant to product acquisition and technology transfer agreements but can also be applied to other types of licensing agreements. In accordance with the analytical framework, improvements are discussed in the context of five steps; the outcome of each is dependent on the determinations made in the preceding step.

In this analytical framework, the first step requires one to consider the nature of the underlying agreement and the rights being
conveyed. The second step requires definition of the rights that are being conveyed. The third step involves the determination of whether the rights to future improvements are included in the conveyance while the fourth step involves definition of the improvements. Finally, the last step requires consideration of the terms and conditions under which the improvements are conveyed. The elements of each of these steps are further discussed below.

B. Nature of the Agreement

In the first step of analysis, the parties to the licensing agreement must identify the nature of their agreement. This is critical because the nature of the original licensing agreement may reflect the relative importance of possible improvements to the technology or artistic expression.

For example, certain considerations logically follow in the context of a collaborative research and development agreement where products or improvements are naturally intended and the framework for such research and development efforts are spelled out in detail in the agreement. Typically, such agreements involve a period of time (the "research term") or a discrete research project in which the research and development activities of the parties are conducted with a common aim to produce new product(s) or technologies; the rights to which are conveyed under the agreement. In these agreements, there is typically no issue concerning whether or not new technologies created during the research term are included, but there may be issues concerning the scope of the rights to the new technologies being conveyed.

In contrast, where the purpose of the agreement is to convey rights in an existing product, copyright, or technology, such as a licensing agreement, distribution or other product acquisition agreement, the right to future improvements does not follow as a matter of course and must be carefully addressed. It is quite simple in such agreements to confine the conveyance to the existing product, copyright, or technology since so much attention is naturally given to the development, marketing and distribution of the existing product. It is easy to overlook the issue of future improvements because the existing product is usually the focus of the discussions. Indeed, it may be that no further work on the product is intended at the time of the negotiations. Nevertheless, one should not overlook the possibility that improvements may be made by either the licensor or
licensee. Therefore, the parties should make improvements a subject of the analysis.

C. Product Definition

Simply identifying the nature of the agreement allows the licensor and licensee to determine whether or not they need to be concerned with the possibility of improvements. In the second step of the analysis, each party should concentrate on the definition of rights being conveyed and whether rights to improvements are to be conveyed. Here, attention is on the definition of the product or work being licensed. That definition helps inform the licensing parties' decisions as to whether they should include a provision for handling improvements.

An essential element of the transfer agreement requires a definition of the rights being conveyed. Usually this involves a precise description of the licensed product and any surrounding technology that is required to allow the licensee to gain the benefit of her bargain. The definition obviously should be drafted in a manner that adequately describes the product or technology that the licensee intends to market, and particularly in the case where exclusive rights are being conveyed, the definition should be broad enough to provide the exclusivity intended. It does no good to provide exclusive rights where the product or technology is so narrowly defined that minor variations of the product can be excluded from the license and that rights to such minor variations can be conveyed to another party. Such a scenario naturally defeats the exclusivity for which the licensee is looking.

In the context of a collaborative research and development (R&D) agreement—particularly where the parties conducting the research have multiple, simultaneous research programs and not all of the research is intended to be included—it is critical to precisely define the products or technologies that are being conveyed. This can be a challenge because the results of the research do not yet exist. Having a clear definition of the research plan, preferably appended to the R&D agreement, is beneficial since one can then refer to the research plan for the conveyance. However, precisely defined research plans are not always possible. Furthermore, the parties conducting the research may intend it to be limited to only those products arising from the research that fall into certain fields of use. In such a case, a field of use restriction is often included in the definition.
For example, it is common in the context of a research collaboration for the parties to include in the license grant:

(1) existing products useful in the Field; and

(2) products developed during the Research Term that are useful in the Field.

In such a case, consideration should also be given to including within the grant potential products that have not yet been developed or identified but that may fall within the scope of any patents filed on the actual products developed. As such, a third category should be included covering any product useful in the field, the manufacture, use or sale of which would infringe a claim of a patent covering a product in categories (1) and (2).64

Where the agreement concerns the rights to a specific product, the product definition is more likely to be specifically tailored to a description of the product itself. A technical description of the product may suffice in most cases, and the issue of rights to improvements may be dealt with in a separate clause as discussed below. Alternatively, the product definition can be drafted broadly so that it would cover any likely improvements that might occur. One way to approach this is to determine whether patent claims that cover the product exist and evaluate whether the product can be defined by reference to the claims of the specified patents. If the claims have appropriate scope, they may provide a logical description of the rights that are intended to be conveyed with broad enough scope to cover any foreseeable variations, modification, or improvements. For instance, a definition of licensed products may refer to the "licensed patents" as follows:

1.00 LICENSED PATENTS means:

(a) the patents and patent applications listed in Schedule 1 and any divisions, continuations, continuations-in-part, reissues, reexaminations, extensions or corresponding patents and patent applications that are filed in any country of the Territory; and

(b) any patents which contain claims, the practice of which would infringe the claims of the patents listed in (a) above which are owned by the LICENSOR or under which the LICENSOR has

64. See infra Appendix, Model Clause 1.13.
the right to grant a license or assign rights in
during the term of the Agreement.

Variations of the wording are possible, but if the patent claims
have sufficient scope, then rights to improvements would necessarily
be included if the manufacture, use or sale of the improved product
would infringe the patents listed.65

Reference to the patent rights as set forth above is not always
possible. There may be no patents to which to refer, or those that
exist may not be satisfactory for defining the product. Further, the
licensor may have no intention to grant rights to the full scope of the
patent claims where multiple products, subject to separate
development, are possible under the claims. In such a case, either a
field of use restriction or a technical description of the licensed
product will have to suffice; but attention to the scope of the technical
description can be used to capture foreseeable improvements. For
instance, where a chemical compound is described, reference to its
“salts, isomers, esters, metabolites, pro-drug forms” and the like can
be referenced. To the extent that these are scientifically determinable,
they are useful terms to expand the scope of the description. The use
of ambiguous terms such as “analogs, derivatives, modifications,
variations, improvement” and the like should be avoided absent
clearer definition of those terms. What is merely an analog or
modification to one person may be completely different product to
another.66

Another possibility is to define the product according to a
particular field of use. In this manner, one can use a broad
description of the field, e.g., “all products useful for ___,” to describe
the rights being conveyed. Accordingly, any such products in the
defined field under which the licensor has rights would be included in
the grant.67 One should be careful, however, to avoid inadvertently
splitting fields so that products marketed by the licensor or third
parties outside the field of use granted to the licensee spill over into
the licensee’s field of use by the consumer, thereby creating an
infringement or breach of contract claim. With attention to properly
defining a particular field of use, the licensor and licensee can
determine what rights are being conveyed.

65. See infra Appendix, Model Clauses 1.01–1.02.
66. See infra Appendix, Model Clauses 1.03–1.10.
67. See infra Appendix, Model Clauses 1.11–1.12.
The circumstances surrounding each individual case will determine what approach is used for defining the licensed product. The issue of future improvements will be a factor in the product definition.

D. Deciding Whether to Include and Then Define Improvements

If the parties do decide that an improvements clause should be drafted into the agreement, then they must agree to a clear definition of such. As the court in *Deering Milliken* noted, "clear, deliberate, and appropriate language" is critical when drafting improvement clauses. Consequently, the third and fourth steps in this analysis focus on the definition of "improvements" and the parameters surrounding it. Unfortunately, very few drafters give much attention to the definition of "improvements." Such an oversight can be very costly as seen in *U.S. Valves.*

As stated, in defining the product rights being conveyed, the rights to future improvements must be considered. In determining whether future improvements are to be included in the original licensing agreement between licensor and licensee, several factors should be evaluated, such as:

(a) the costs to the licensor for making the improvements;
(b) the incremental costs that the licensor will want to charge the licensee for the improvements;
(c) whether any diligence for developing the improvements will attach to the licensee;
(d) the exclusivity of rights to improvements; i.e., will the rights be exclusive or non-exclusive;
(e) the extent of ongoing research and development by the licensor; i.e., if there is little likelihood of continuing research and development, perhaps it would be better for the licensee not to press for broad rights if the incremental costs are too high;
(f) whether reciprocal grantbacks are likely; i.e., whether licensee will provide licensor with rights to any improvements she makes;
(g) the impact of improvement rights on warranties and indemnifications, particularly non-infringement

68. See supra note 29 and accompanying text.
69. See supra notes 30–31 and accompanying text.
representations by the licensor since the licensor will be unlikely to make warranties and representations concerning unknown future products;

(h) whether improvements should automatically be included, or only included at the licensee's option.

All of these factors need to be weighed in the negotiations with some militating towards including improvements while others militating against the inclusion of improvements.

Once it has been determined that improvements will be included, the difficult task is to define what constitutes an "improvement" of existing products subject to the license and what constitutes separate products not subject to the license. In this fourth step of the analysis, attempts should be made to distinctly define what are and what are not improvements, but in the end, there will be some circumstances where adequate definition is impossible. The parties may therefore prefer to include specific language in the improvements clause setting forth a dispute resolution process for deciding the issue, preferably by arbitration before an experienced arbitrator in the field.

Even if the agreement is a collaborative R&D agreement where the licensed technology is defined by the research results, the issue of improvements made after the term of the research should be addressed. If the parties continue research and development independently after the end of the research term, improvements may be made that are based upon the results of the collaboration. Thus, improvements should still be considered in such case, typically for at least a period of time that constitutes the "tail" to the end of the research term.

There are numerous ways to approach the definition of improvements. One way was discussed earlier; i.e., to expand the product definition to include future improvements. Alternatively, a separate definition of improvements can be employed. As discussed below, several approaches are possible.

1. Functional

In this approach, the improvement is described functionally in accordance with the manner in which the improvement adds to the licensed product. For example, the improvement can be defined as all modifications or variations of the licensed product to which the licensor or licensee has the rights, that also contributes to the licensed product in any of the following ways:
(a) improves the performance of the licensed product in a defined way;
(b) reduces the manufacturing costs of the licensed product;
(c) reduces costs for materials or components or reduces production time or steps;
(d) reduces side effects or improves tolerance or decreases toxicity;
(e) improves delivery or accessibility of the product to the consumer;
(f) broadens the applications or spectrum of use for the product;
(g) increases the marketability of the product; or
(h) would otherwise replace the licensed product or compete with the licensed product in the market for which the licensed product is intended.

2. Infringing Improvements

Another way to approach the definition of improvements is to refer to the existing patent rights and include any modification or variation of the licensed product, the manufacture, use or sale of which would infringe the licensed patents. Regardless of whether an improvement is separately patentable, a determination can be made as to whether the manufacture, use or sale of the improvement may be dominated by the original broad patents. Under this scenario, the improvement would be included if it were covered by the claims of the defined licensed products.\footnote{\textit{See infra} Appendix, Model Clauses 2.0 and 2.3.}

This scenario requires a thorough analysis of the existing patent rights and a determination concerning the scope of the claims. In a case where the claims are narrowly drafted, this approach may not be satisfactory since minor variations may be enough to avoid the claims. In such an event, the licensee or licensor may not be satisfied with the scope of the improvement rights.

3. Technical Description

Where the manner in which improvements may be made is foreseeable by the parties, an attempt may be made to technically define the kinds of improvements that are to be included. Those most familiar with the technology should be consulted for guidance. For
example, where it is foreseeable that derivatives or analogs of a licensed chemical compound may be made, an improvement can be defined as

(a) a compound which results from a chemical synthesis program based on the Licensed Compound;
(b) is based on structure-function data derived from the Licensed Compound, which data is not in the public domain;
(c) is synthesized using the Licensed Compound or any progeny thereof.\(^7^1\)

4. Field of Uses

As discussed above, a field description can be used to define the improvements. Thus, any further products in the field would be subject to the improvement clause. Careful attention to the scope of the field definition is required and the possibility of new uses and applications considered.\(^7^2\)

5. Other Considerations

Other considerations that may be addressed by the improvement definition include whether or not the improvements are patentable. If the improvement must be patentable to be subject to the improvement clause, then it should be stated as such. Conversely, if the improvement must be one that is not separately patentable, it too should be stated. A compromise may be appropriate where non-patentable improvements are included but separately patentable novel and nonobvious improvements are not included.

If non-patentable novel improvements, such as trade secrets, are intended, then provisions requiring the parties to maintain confidentiality of the improvements should be stated. Such provisions will help preserve the right to enforce any trade secret or rights involved.

When considering improvements in the context of a non-exclusive license, the possibility of gaining access to improvements made by other licensees should be evaluated. If the licensor has access to such improvements and has the right to pass such improvements along to other licensees, the licensee will typically

\(^7^1\) See infra Appendix, Model Clauses 1.03–1.10.
\(^7^2\) See infra Appendix, Model Clauses 2.1–2.2.
insist that such improvements be included. Where such benefit is conferred without further charge, a reciprocal obligation to provide improvements could be imposed on the licensee. Likewise, where the licensor obtains rights to other third party developments, whether by license or acquisition after the date of the agreement, the licensee may bargain for access to such third party developments. Where the licensor has the right to sublicense the technology, the right can be included either on a direct pass-through basis; i.e., included in the license, or under other conditions; i.e., on a separate royalty bearing basis. In either case, the licensor may insist that the sublicense be conditioned on the licensee satisfying her duties under the third party license to the licensor (including the payment of royalties). Also in the context of a non-exclusive license, the impact of granting rights to improvements on any “most favored licensee” provisions in other contracts will have to be addressed.

E. Terms for the Improvements

Once it has been determined that future improvements are to be included in the licensing agreement, and the improvements have been defined, the fifth, and final, step requires that attention be turned to the terms under which the improvements will be conveyed.

Several alternatives are possible. One possibility is that the improvements can be incorporated under the terms of the existing agreement so that the licensee will market the improved product under the same terms and conditions and pay the same royalties as originally contemplated under the agreement. However, the licensor may feel that this is unsatisfactory since it would not provide any incremental reward for the additional expense and effort expended when making the improvement. Accordingly, the licensor may wish to have the opportunity to seek additional consideration for the rights to the improvements.

Likewise, the licensee may not always wish to have the improvements included in the license since the addition of improvements may have certain implications on the licensee’s obligations. For instance, if the license is an exclusive one, the licensee may have obligations to exploit the improvements and to make efforts to develop and commercialize them. Ordinarily, the licensee would like to have the freedom to pick and choose what improvements she wants to invest in and implement. Further, the inclusion of improvements may have the effect of extending the duration of royalty obligations, particularly if the improvements are
separately patented and the royalty duration is tied to the life of the patents. The licensee may have the right to terminate the license to the improvements and disengage by giving notice, but this is more complicated where disclosures of confidential information or trade secrets concerning the improvements are involved.

Therefore, several typical provisions can be employed to address the scenario where the rights to improvements will be included only at the option of the licensee or under different terms. These include the right of first refusal, an option exercisable for a limited time period, a duty to disclose and negotiate in good faith or under specified terms, a duty to license improvements in a non-exclusive license under “most-favored-licensee” terms, or an obligation on the licensee to reimburse or share some of the research and development expenses spent by the licensor in developing the improvements.

Typically, the licensor and licensee have different perspectives concerning the obligation to include rights to improvements. The licensor may consider it unfair that the licensee continues to reap the benefit of the licensor’s ongoing research and development efforts. Conversely, the licensee does not want to face the possibility of her product becoming obsolete because of improvements made by her own partner. These concerns are true, but reversed, if the licensee is the primary developer of improvements.

One way to resolve this conflict is to establish a cut-off date for the inclusion of improvements. This way the licensor does not need to perpetually provide improvements, but the licensee can gain the benefits of the improvements and be protected from being rendered obsolete at least for some period of time. Thus, a cut-off date of five years from first commercial sale of the product may be a reasonable compromise.

Where the cut-off date is employed, consideration must be given to defining the point at which the obligation to communicate the improvement is triggered. The licensor may only have an obligation to convey improvements that reach a certain level of development prior to the cut-off date. For example, the licensor may resist having to convey rights to improvements that are nascent, undeveloped, or at a conceptual state prior to the cut-off date and may only want to convey rights to more developed technology. Reference to improvements “conceived” and “reduced to practice” prior to the cut-off date is at least one way to address the issue.

In any event, where improvements are conveyed, it is necessary for the improvements to be communicated to the licensee in an effective manner to allow the licensee to practice the improvements. Accordingly, provisions should be included to ensure adequate transfer of the improvement to the licensee, including for instance, access and visitation rights to the licensor's facilities. The provision concerning plant visits should specify the frequency of the visits, the type of authorized personnel for the visit, and the confidentiality of the information gained.

Additional provisions should be considered that require the licensor to provide assistance and training to licensee's employees to enable the licensee to practice the technology, albeit at the licensee's expense.

It may be in the licensor's interest to include provisions specifying the circumstances under which the duty to provide improvements would be suspended or terminated. For instance, the licensor may want to be able to suspend his obligation in the event of a breach of performance by the licensee, particularly if there are diligent performance obligations, or in the case of an attack on the validity of the licensor's intellectual property by the licensee. The licensor may also wish to suspend rights to improvements in the event of other specified acts or omissions that may not constitute breach of the agreement but that may cause the licensor to desire to avoid giving further improvements; e.g., product safety recalls, misrepresentations by the licensee, mislabeling and the like.

**F. Non-Compete Provisions**

Even if the parties are unable to agree that improvements should be included, consideration should be given to whether certain non-compete provisions preventing the licensor from entering into competition with the licensee should be included in the licensing and R&D agreements. While this would not ensure the licensee access to the improvements, it would provide a stalemate so that the licensor could not use the improvements to compete with the licensee and possibly render the product marketed by the licensee obsolete.

Several considerations enter into proposing such non-compete provisions. Foremost, the licensee must consider whether asking for the non-compete provisions will trigger the licensor's request for a personal visit to his facilities or for@@
reciprocal non-compete provision. The licensee may want to retain her freedom to sell other competing products in the field.

Further, in the context of international agreements affecting the European Union, non-compete provisions where one party is restricted from competing within the common market with respect to research and development, production, use or distribution of competing products, may violate the competition laws of the EEC.75 Such provisions are generally blacklisted under the Technology Transfer Block Exemptions and prohibited. One exception to this allows the licensor to reserve the right to terminate exclusivity granted to the licensee and stop licensing improvements if the licensee enters into competition with the licensor. No such exemption exists for a non-compete obligation imposed on the licensor. Accordingly, such provisions may not work for international agreements. Further, under certain circumstances, such provisions may have antitrust implications in the United States.

V. CONCLUSION

The simple five-part analytical framework set out herein strives to provide a more structured approach to drafting improvements clauses. As seen in arbitration and case law, improvement clauses can prove incredibly important to a licensor and licensee. Nonetheless, there are several challenges that arise when trying to negotiate such clauses. Consequently, practitioners require a better way of thinking about these clauses. The discussed analytical framework attempts to provide better direction and structure to overcome these challenges. Going forward, improvement clauses will hopefully receive the due attention they have earned.

APPENDIX. MODEL CLAUSES IN CONTEXT OF PHARMACEUTICAL LICENSING AGREEMENT

1. PRODUCT DEFINITIONS

A. By Reference to Licensed Patents

1.01. "LICENSED PATENT" means; (a) the patents and patent applications listed in Appendix __, inventions described and claimed therein, reissues thereof, extensions thereof, and any divisions, continuations or continuations-in-part thereof, and (b) any improvement patents or patent applications owned by LICENSOR, or under which LICENSOR has a right to grant licenses, containing claims the practice of which would infringe the claims of any patent or patent application set forth in (a) above.

1.02. "LICENSED PRODUCTS" means any product or part thereof manufactured, used, distributed or sold by LICENSEE, an AFFILIATE or SUBLICENSEE which:

(a) Is covered by a valid claim of an unexpired LICENSED PATENT; or

(b) Is otherwise adapted for use in the practice of a method covered by a valid claim of an unexpired LICENSED PATENT.

A claim shall be presumed valid in accordance with the first paragraph of 35 U.S.C. § 282 unless and until it has been held to be invalid by a final judgment of a court of competent jurisdiction from which no appeal can be or is taken.

B. By Product Description

1.03 LICENSED PRODUCT shall mean any COMPOUND, PRODUCT or COMBINATION PRODUCT.
1.04 "COMPOUND" shall mean the compound ________, and its pharmaceutically acceptable salts, esters, isomers, metabolites, and pro-drug forms.

1.05 "PRODUCT" shall mean any pharmaceutical product that contains a COMPOUND and no other active ingredients for use in the FIELD.

1.06 "COMBINATION PRODUCT" shall mean any pharmaceutical product that contains a COMPOUND and one or more other active ingredients.

1.07 "LICENSED PRODUCT" shall mean any product containing as an active ingredient a COMPOUND, a CLOSE STRUCTURAL ANALOG or a DERIVATIVE.

1.08 "COMPOUND" shall mean the compound ________, and its pharmaceutically acceptable salts, esters, isomers, metabolites, and pro-drug forms.

1.09 "CLOSE STRUCTURAL ANALOG" shall mean, with respect to a COMPOUND, another compound, which (a) is claimed in a patent application or patent within the PATENT RIGHTS which claims COMPOUND, and is in the same chemical genus as the applicable COMPOUND and (b) has activity against the same molecular target as the COMPOUND.

1.10 "DERIVATIVE" shall mean a compound the rights to which are owned by LICENSOR which (a) results from a chemical synthesis program based on a COMPOUND, or (b) is based on structure-function data derived from COMPOUNDS, or (c) is claimed or contained within a chemical genus, as defined in any issued VALID CLAIM within the PATENT RIGHTS, or in a VALID CLAIM within the PATENT RIGHTS of a pending application for such a patent which application is being prosecuted in good faith, and as to which one member of such chemical genus is within (a), or (b) above. For purposes of determining whether a given composition is a DERIVATIVE, it is understood that a compound which meets one or more of the foregoing criteria and is discovered, identified, synthesized or acquired on or before the CUTOFF DATE, shall be included as a
DERIVATIVE notwithstanding whether the composition was identified by LICENSEE as being active after the CUTOFF DATE.

C. By Field Of Use

1.11 "LICENSED PRODUCT" shall mean any product useful in the FIELD the rights to which are owned by LICENSOR, or to which LICENSOR has the right to grant licenses to, during the term of this Agreement.

1.12 "FIELD" shall mean ________________.

D. In Collaborative Research Agreements

1.13 "COLLABORATION PRODUCT" means, except as provided below, a [Product] [composition of matter, including, but not limited to, chemical entities and fragments thereof, prodrugs, peptides, non-peptides and monoclonal antibodies] that (a) is useful in the Field; and (b) either:

(i) is discovered, identified or synthesized by or on behalf of LICENSOR or LICENSEE, and is recognized for its utility in the Field, as provided below, as of the Effective Date or prior to the first anniversary of the end of the Research Term by or on behalf of LICENSOR or LICENSEE; or

(ii) is acquired by LICENSOR or LICENSEE from a Third Party, on an absolute or contingent basis (such as rights under an option), and which is recognized for its utility in the Field, as provided below, as of the Effective Date or prior to the end of the Research Term; or

(iii) is contained within the genus as defined in any granted claim of any unexpired Patent as to which one member of such genus is defined in (i) or (ii) above.
2. IMPROVEMENT DEFINITIONS

2.0 Infringement Criteria

"Improvement" shall mean any derivatives, adaptation, change, modification, or redesign, of Licensed Products or any manufacturing apparatus, intermediates or processes used to make Licensed Products, which would, if made, used or sold by an unlicensed entity, infringe one or more claims of a Licensed Patent.

2.1 Field Criteria

"Improvement Products" shall mean any Products in the Field, other than the Initial Products (define), including, without limitation, analogs, derivatives, modifications, adaptations, progeny thereof, or changes in the indication, formulation or dosage of the Initial Product.

2.2 Mixed Criteria

"Improvement" shall mean any and all of the following to the extent made, licensed or acquired by LICENSOR during the term of this Agreement: (a) an improvement upon or modification to the inventions and discoveries disclosed or claimed in any of the Existing Patents; (b) an improvement upon or modification to any of the Existing Know-How; and (c) any other product useful in the Field.

"Product Improvement" shall mean (a) any improved, redesigned or modified version of the Product, or (b) the use, without substantial modification, of Product to perform a function not initially intended for it.

2.3 Miscellaneous

"Improvements" means any change with respect to the Product for use in ____________, including without limitation, any change in formulation, dosage or mode of delivery, any additional indications and any change in the Product resulting from a change in the manufacturing process.
3. TERMS FOR IMPROVEMENTS

3.1 Improvements
Any Improvements developed during the term of this Agreement by or on behalf of a Party shall be owned by the Party or Parties whose employee(s), contractee(s) or designee(s) would be deemed to be the inventor under U.S. patent laws. Any Improvements relating to the Product made after the Effective Date relating to the Field by or on behalf of the LICENSOR shall be deemed to be included in the Product for all purposes under this Agreement. Without in any way limiting the foregoing, the LICENSEE shall have the exclusive license to commercialize any such Improvements made by the LICENSOR, subject to the other terms and conditions of this Agreement; provided, however that if the LICENSEE breaches this Agreement, becomes insolvent or undergoes a change in control (as defined in Section ___), no such licenses to Improvements shall be granted.

3.2 Development of Improvement Products
(a) If either Party desires to develop an Improvement Product, it shall submit a proposal for such development to the other party, which shall include a proposed development plan, together with all material information available to the proposing Party to indicate whether such development would be worthwhile. The non-proposing Party shall determine within 90 days of receiving such proposal whether it desires to proceed with such development. If it does, then the parties shall adopt an Improvement Product Development Plan and Budget, which shall describe the overall program of Development, including but not limited to toxicology, formulation, chemical process development, clinical studies, regulatory plans and other elements of obtaining Regulatory Approval. The Improvement Product Development Plan and Budget shall include projected timelines for Development and regulatory events, and estimated Shared Development Expenses, and shall specify Party-specific execution responsibilities in the respective territories. Following adoption of the Improvement Product Development Plan and
Budget, development of such Improvement Product shall proceed.

(b) If either Party elects not to proceed with Development of the proposed Improvement Product, then neither Party shall conduct any Development, or manufacture or sell the proposed Improvement Product anywhere in the world, without the other Party’s written consent.

4. ACCESS TO IMPROVEMENTS

4.1 LICENSOR shall furnish LICENSEE promptly after the Effective Date all Know-How which is necessary or useful to enable LICENSEE to exploit its rights under this Agreement. LICENSOR shall promptly identify to LICENSEE and disclose to LICENSEE, during the term of this Agreement, all additional Know-How and Improvements which could relate to making, developing, using or selling Product and Improvements licensed hereunder, to which LICENSOR or its Affiliates have or obtain rights, and such Know-How and Improvements shall be automatically deemed to be within the scope of the licenses herein granted without payment of any additional compensation. LICENSOR shall provide reasonable technical assistance at no additional cost to enable LICENSEE to utilize such additional Know-How and Improvements if LICENSEE elects to do so; provided that LICENSEE shall promptly reimburse LICENSOR for any out-of-pocket expenses incurred by LICENSOR in providing such assistance.

4.2 Additional Terms: Exclusivity; Non-Competition Within the Field

During the Research Term, LICENSOR or its Affiliates shall not directly or indirectly, conduct, have conducted or fund any research, development, regulatory, manufacturing or commercialization activity within the Field, except as is permitted pursuant to this Agreement. In addition, during the Research Term, (a) LICENSOR shall disclose to LICENSEE on an ongoing basis all of its activities within the Field, and (b) LICENSOR shall not, without the prior consent of LICENSEE, hold any discussions with any Third
Party relating to activities within the Field, regardless of whether such activities would take place during or after the Research Term. Except as specifically provided herein, all activities of the Parties outside of the Field are outside of the scope of this Agreement.