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TO PROMOTE THE PROGRESS OF USEFUL ARTICLES?: AN ANALYSIS OF THE CURRENT UTILITY STANDARDS OF PHARMACEUTICAL PRODUCTS AND BIOTECHNOLOGICAL RESEARCH TOOLS

PHANESH KONERU *

* LL.M., Columbia University School of Law (1998); J.D., University of San Diego School of Law (1996); Ph.D., University of Southern California (1992). Admitted to practice before the United States Patent and Trademark Office. The author is grateful to Professor Harold S.H. Edgar, Julius Silver Professor in Law, Science, and Technology, Columbia University School of Law for his invaluable guidance and discussions on this article. However, any errors, omissions or misstatements should be attributed to the author alone. A substantial version of this article is part of the author's LL.M. Essay submitted in partial fulfillment of the LL.M. degree at Columbia University School of Law. As a student of patent law, I dedicate this work to the Honorable Judge Giles S. Rich, for his outstanding contributions, extraordinary vision and courage in defining and shaping the United States patent law over his long, illustrious career.

I. Introduction

The patent clause of the U.S. Constitution n1 requires that in return for a patent grant the invention must promote the progress of useful arts. This much is indisputable. The current state of patent law does not,

[*626] however, appear to support the converse proposition that an invention that promotes the progress of useful arts must get a patent, even if it meets the statutory criteria of novelty and nonobviousness. The Patent Office's ruling in Ex parte Aggarwal n2 reflects this view most clearly: "There is no question that appellants have made an important discovery with regard to chemical compounds (proteins) which are the subject of serious scientific investigation but [a patent cannot be granted because of its] unverified and speculative utility." n3

Even though the Aggarwal ruling may seem contradictory to the uninitiated in the complexities of patent law, it is but a simple and direct application of Brenner v. Manson, n4 where the Supreme Court held that an invention must offer "specific benefit in currently available form" n5 to satisfy the statutory utility requirement. n6 Accordingly, a chemical process that produces a chemical intermediate has no patentable utility and thus is not patentable if that intermediate is useful only as a research tool. n7 Manson, by requiring that every patentable invention must be immediately useful to society, converts the purpose behind the constitutional clause from promoting progress in useful arts into promoting progress in useful articles only.

This exclusive focus on useful articles reflects a fundamental misunderstanding of how progress in useful arts may be made. According to Judge Rich, true progress may come from the knowledge a disclosed invention brings to the society. n8 While abandoned applications cannot

[*627] help promote the progress of useful arts, neither can the inventions that have never been filed or disclosed for one reason or another. By itself, an invention may appear to be useless. However, upon prompt disclosure, the invention could immensely enrich the useful art to which it belongs and that enrichment could be the utility of that invention.

Encouraging early disclosure is one of the fundamental objectives of the patent system. Early disclosure helps to: minimize enablement issues under

112; establish an earlier reduction to practice and thus help the inventor to prevail in an interference under

102(g); potentially reduce the number of joint inventors and thus reduce both prior art and joint inventorship problems under

116; simplify operability questions under

101. n9 A patent system that grants patents only to useful articles discourages early disclosure of inventions that are otherwise technically meritorious until the inventor can establish a "practical use" for her invention. This discouragement of early disclosure is antithetical to the objectives of a patent system because it impedes progress in the art n10 and undercuts the rationale of a patent system because many inventions of significant commercial utility would be disclosed to the public sooner or later without the incentive of a patent grant.

Manson's focus on present utility, demanding that society must incur some immediate tangible benefit in return for granting a patent is advantageous in that the current worth of the invention can be measured more accurately than the future worth, which is uncertain. Put differently, the central disagreement between Manson and Judge Rich's views of the patent law's quid pro quo is one of timing. However, one cannot help but analogize Manson's view of denying a patent when the future worth of an invention is uncertain to that of the fabled owner of the goose that laid golden eggs. As the story goes, one day the owner killed the goose to have the "immediate benefit" of collecting all the golden eggs at once, rather than waiting for the goose to lay them one at a time. This article cautions against demanding immediate returns from the patent system because real progress in useful arts could be discouraged. While it is difficult to establish a causal relationship without thorough empirical studies, this concern may be real in view of the most recent report that patent applications for biotechnological inventions have declined to 50% of the expected number for the year. n11

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The general perception in the patent bar may be that recent lower court rulings have softened Manson considerably and that Manson has no teeth. However, closer examination of cases such as Cross v. Iizuka n12 and In re Brana n13 reveals otherwise. n14 Moreover, it is doubtful whether a competent patent attorney would confidently submit a patent application today on a biotechnological invention that has no known use other than as a research tool, without wondering about the risk of rejection from the Patent Office for lack of utility.

This article is concerned with two highly important areas of research where the effects of Manson are felt most - research involving pharmaceutical and biotechnology products and research intermediates. By focusing on these inventions, this article explores the economic and doctrinal implications of the current utility standard. Part II of this article presents a brief overview of current economic theories of the patent system. Taking the concept of rent dissipation as a suitable criterion for economic efficiency, it argues that encouraging early disclosure minimizes rent dissipation at various stages of invention and improves the economic efficiency of the patent system.

Parts III A and B analyze the Manson standard and conclude that the standard is doctrinally unsound and is economically inefficient. Part III C analyzes the Cross and Brana standards, which address the utility of pharmaceuticals. Part III D concludes that the two current standards are only a partial solution and that a lower standard is more economically efficient, given that the Food and Drug Administration ("FDA") has the exclusive authority to determine what is "useful" for human therapy. Part III E analyzes the patentability of biotechnology research intermediates and argues that denying patent protection to such products is inconsistent with the objective of promoting the progress of useful arts.

[*629] This article concludes in Parts IV and V that a more relaxed concept of utility truly promotes the progress in useful arts.

II. From Rewards to Rents: The Economic View of the Patent System

"[T]he overall conclusion is that currently there is no unifying theory that describes the overall patent system and the outcome of individual cases." n15

Patent law as an ever-evolving body of perplexing rules and policies poses a formidable problem for traditional economic analysis. Several scholars have attempted to rationalize the existence of the patent system and the specific holdings of many cases under various economic theories, hoping to predict the outcome of future cases. n16 Despite claims to the contrary, n17 no one theory successfully provided a unified economic basis for patent law. n18 However, this paper does not aim to predict future cases. Rather, its purpose is to analyze the current practice based on the Brenner v. Manson n19 utility standard for economic efficiency and argue

[*630] that such economic efficiency can and should be achieved by modifying the current practice.

In general, the patent system can cost society in many ways. n20 In light of these costs, scholars have argued whether a patent system is needed at all. n21 While such discussion is beyond the scope of this article, the Constitution appears to have made the deliberate decision in favor of a patent system as the most cost effective inducement to encourage innovation, because granting a patent monopoly would be the cheapest for the government. n22 The monopoly, while offering no direct monetary value, helps the inventor recover her investment by preventing "free riders" from copying the invention. n23

Accepting that granting a patent monopoly is the chosen form of incentive, the next goal is to maximize the benefit of that monopoly to society. Knowledge that a patent system inevitably creates competition

[*631] for the monopoly should prepare us to make such competition economically sensible by reducing the various costs and inefficiencies of the patent system. This necessitates an understanding of our patent system from an economic point of view. Economists have advanced many theories to explain the patent system and to rationalize whether and when an invention deserves a patent. The following is a brief overview of the various theories.

A. The Economic Theories

1. The Reward Theory (Incentive-to-Invent)

The reward theory holds that society should reward an inventor in the form of a patent monopoly for providing an invention to society. n24

While patent monopoly is the best form of reward from society's point of view, n25 it is probably the best reward from the inventor's point of view as well because "the reward is of [the inventor's] own making." n26 The inventor's reward is proportional to the benefit his invention brings to the society. Put differently, the market place, rather than the Patent Office, is the venue where the act of rewarding actually takes place. n27 That is, the patent monopoly is a means, but not a guarantee, for the inventor to profit from his investment. n28 Failure to recognize this true

[*632] quid pro quo can lead to a misunderstanding of the patent philosophy with resultant doctrinal confusion and economic inefficiency. n29

The reward theory has many criticisms. n30 In particular, through the patent monopoly, the reward system creates competition to be the first inventor and this causes needless waste of duplicative effort which goes uncompensated because only the first to complete the invention gets the patent. n31 Another criticism is that the patent system need not reward inventions that are made by accident, because of market demand or for scientific curiosity because they are made for reasons unrelated to the existence of the patent reward. n32 Protecting these inventions would be unnecessary and costly to the public because they would be disclosed to the public eventually. While the argument is appealing on its face, it assumes, perhaps unrealistically, that many nonpatent-induced inventions would necessarily be disclosed to the public without the reward of a patent grant. It is basic patent law that, to be rewarded, the inventor must fully disclose the invention to the public, rather than merely making the invention. n33 The patent laws encourage disclosure of all inventions, even those made accidentally or by minimal effort. This policy is reflected in the statutory statement that "patentability shall not be negatived by the manner in which an invention is made." n34

Current scientific curiosities may not necessarily result in publications as freely as in the past. As research funding by the government at the universities and National Institutes has decreased over the past decade, many inventors and researchers should consider patenting their inventions before publishing them. n35 Thus, the focus should be on

[*633] whether the inventor needs the patent monopoly as an inducement to disclose, not on whether an inventor needs the patent as an inducement to make. So long as the society believes that the inventor needs such inducement to disclose, the society may wish to reward him with a patent.

This exchange-for-secrets theory has been criticized as question-begging in that if an invention can be kept secret, the inventor needs no patent protection and if it cannot, that invention still does not need a patent because the secret will eventually be deciphered. n36 However, the key to this dilemma is that the patent system not only encourages disclosure but seeks early disclosure. The policy seems to assume that no one, in the absence of a conferred benefit, would disclose. When in doubt, the law is willing to err on the side of early disclosure, and this is indicative of the premium that society puts on early disclosure of inventions. n37 This premium on early disclosure appears to be central to the existence of a patent system.

2. The Patent-Induced Theory

The patent-induced theory premises that certain inventions would be made only because the inventors expect patent protection. This is a subset of the reward theory in that the motivation of the inventor is the distinguishing factor. The theory posits that protection should be limited to only those inventions that are patent-induced and that the higher the ratio of patent-induced to nonpatent-induced inventions, the greater the likelihood of societal benefit. n38

The patent-induced theory makes the same argument that inventions that are made regardless of the patent system - those made accidentally or for scientific curiosities - should not be protected because they will eventually be made available to the public free of cost. However, this theory also fails to recognize that early disclosure,

[*634] regardless of how an invention is made, is the primary motive behind the granting of a patent monopoly. Instead, it incorrectly focuses on the motives of the inventor.

3. The Prospect Theory

Professor Kitch defines a prospect as "a particular opportunity to develop a known technological possibility." n39 The prospect theory encourages the granting of patents that have a broad scope so that many improvements can be covered under a single patent. n40 This broad coverage permits the patent owner to coordinate improvements of the invention, which increases the efficiency of the inventive process.

Professors Merges and Nelson refute the contention that the prospect theory's central coordination is efficient. n41 "In principle it could be, but in practice it generally is not." n42 They argue that while competition causes waste, the prospect theory makes unrealistic assumptions about human behavior and that rivalry is better. n43 The prospect theory arguably may not apply to biotechnology inventions because central coordination, a necessary event for prospect theory, requires predictability of science, and biotechnology inventions are unpredictable. n44 However, this argument is not entirely convincing because such unpredictability can be factored into licensing arrangements.

4. The Race-to-Invent Theory:

Merges and Nelson propose an economic theory based on the premise that "when it comes to invention and innovation, faster is better." n45 Merges and Nelson advocate limiting the broad scope of pioneering patents so that competition for improvements on those

[*635] pioneering patents can be maintained. This approach has been criticized as "antipatent" because it provides less incentive to invest in revolutionary inventions which typically need huge investments. n46 An additional criticism was that in a race-to-invent system one does not need patent protection because "market- induced incentives, such as lead-time, market recognition and learning curve advantages would provide adequate incentives for racing inventions to the market place." n47 However, this criticism applies to all economic theories, and not necessarily to just the race-to-invent theory.

While the race-to-invent theory was developed in the context of patent scope analysis, its applicability is much broader. It appears to be the first economic theory that indirectly takes into account the patent policy of encouraging early disclosure.

5. The Rent Dissipation Theory

Rent is an economic term of art and roughly means profits. n48 Grady and Alexander consider that patent monopoly is a rent the society is willing to pay the inventor for disclosing his invention where the benefit to the society exceeds the developmental costs of the invention. n49 The rent (patent monopoly) protects inventors from imitators. However, the patent system, by granting the monopoly, also provides others with an incentive to compete with the patent holder for that monopoly, causing wasteful or redundant expenditure called rent dissipation. Grady and Alexander argue that courts interpret the patent law in ways that minimize this rent dissipation by appropriately granting or rejecting patents. n50

Grady and Alexander consider an invention "elegant" if it is incapable of further improvement. n51 They argue that because elegant inventions do not signal further improvements, there would be no rush by inventors to improve on the elegant invention, and thus there would be no rent dissipation. n52 Consequently, such elegant inventions do not need

[*636] to be protected. As the theory goes, the discovery by Dr. Morton of ether's utility as an anesthetic is considered an elegant invention and thus was correctly decided as unpatentable. n53 According to the theory, "[m]ost likely to receive patent protection are inventions that, although of comparatively small value, nonetheless signal a large potential for improvement." n54 Grady and Alexander claim that their theory explains not only the basic policies of the system but also "actual patent rulings better than the rules and tests applied by the courts." n55 This assertion as well as the basic aspects of the rent dissipation theory have met with significant criticism. n56

B. Rent Dissipation as a Criterion for Economic Analysis of the Patent System

Despite the rent dissipation theory's several conceptual and practical problems in rationalizing patent cases, it offers a convenient framework to analyze the economic efficiency of the individual doctrines in the patent system because it allows us to isolate and analyze how each doctrine contributes to or decreases rent dissipation at various stages of

[*637] the inventing process. n57 In essence, this article argues that the Grady-Alexander hypothesis of limiting rent dissipation should be the goal for future administration of the patent system while rejecting the Grady-Alexander claim that the administration in the past has always succeeded in that goal.

Before undertaking further analysis of patentability doctrines, it should be noted that "it is far from clear that all rent dissipation is bad." n58 Put differently, rent dissipation cannot be analyzed in a vacuum and should be considered in view of whether the rent dissipation is created by healthy competition. n59 Similarly, the market demand for a patented product determines whether competing for that monopoly is rent dissipation or competition. However, such a determination is difficult to make at the time of granting a patent. The Patent Office neither possesses the expertise to engage in such market predictions nor does it require market projections before deciding on patentability issues. But surprisingly, the Patent Office de facto appears to engage in such predictions when it makes "practical utility" determinations under Manson. n60

According to Grady and Alexander, rent dissipation can occur at three distinct stages: (1) at the conception stage where several inventors could be independently working to solve a problem, even though the patent system rewards only the first inventor to complete; (2) at the improvement stage where the primary invention can "signal" possible

[*638] future improvements and induce many inventors to compete to make those improvements; and (3) at the strategic decision making stage where the inventors expend resources to keep the invention secret by choosing not to rely on the patent system. n61

1. Rent Dissipation at the Conception and Improvement Stages

Every commercially successful product or process invites competition to find alternatives and improvements, and thus causes rent dissipation at both the conception and improvement stages, even without a patent system. n62 Though the patent system encourages rent dissipation by creating competition for the monopoly, it helps to reduce the rent dissipation at the conception stage significantly by inducing and making early disclosure possible. By knowing that a certain product has already been made and patented (i.e., that a particular solution has been reached), the competition can save resources that would otherwise be expended in making the same product. The "race-to-invent" and thus the "race-to- disclose" minimizes rent dissipation at the conception stage. The patent law policy of promoting early disclosure is economically efficient and should be vigorously encouraged.

In the case of expenditure on improvements, it is unclear whether this expenditure should be called rent dissipation. As the number of ways in which a product can be improved decreases, rent dissipation increases, and is most acute when that number is zero. On the other hand, it may not be rent dissipation when the product can be improved in many ways, each resulting in a new product or use in a different field of activity. The law, apparently recognizing such activity to be beneficial, encourages improvements of a product leading to multiple uses by offering protection to the discovery of new uses of old products. n63 Moreover, efforts to discourage improvements in order to minimize rent dissipation can potentially lead to the problem of "underfishing." n64

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2. Rent Dissipation Due to Secrecy

Grady and Alexander gave rent dissipation due to secrecy only cursory treatment. n65 As the following discussion indicates, this topic deserves closer attention. Secrecy can cause rent dissipation in at least three different ways. The first type of dissipation occurs when the inventor, after making an invention, expends resources in keeping it secret ("keeping-secrets loss"). n66 The second type occurs when competing inventors know that an invention has been made and they try to unlock the black-box or engineer around the secret to reach the same end result ("unlocking-secrets loss"). The third type occurs when the competition, assuming that a certain invention has not been made, continues to expend resources but in fact the invention has been made but kept secret. The rent dissipation in this case manifests itself as the expenditure by the competition at the conception stage. To reflect its hidden nature, this rent loss can be called, for lack of a better descriptive term, "latent loss."

The latent loss is distinct from the rent dissipation at the conception stage: the invention has not been made yet in the latter case (and thus the society can justify the continued expenditure of resources during that stage), whereas the former loss occurs even after the invention has been made. As a result, the latent loss represents expenditure by the entire pool of inventors excluding the first inventor who made the invention (but kept it secret), whereas the rent loss at the conception stage includes expenditure by that inventor as well. The latent loss can be significant and can approach the rent dissipation at the conception stage, depending on how early in the search the invention was made and kept secret. Because the latent loss involves continued expenditure by one or more competitors to make the invention, it can be much greater in value than the keeping-secrets loss.

While all three types of rent loss due to secrecy can arise irrespective of the existence of the patent system, a well-administered patent system is perhaps best suited to minimize each type of rent loss, assuming that the inventor desired to seek patent protection. n67 The rent

[*640] loss due to expenses incurred to keep the invention secret (keeping-secrets loss) and the latent loss can be most effectively minimized for many types of inventions by inducing early disclosure with a patent grant. The rent loss that arises due to reverse engineering is minimized or virtually eliminated by the patent system because the invention is published once a patent is granted. n68 Because this rent loss involves the patent law doctrine of enablement, its further consideration is beyond the scope of this article.

Many factors such as the characteristics of the invention, market competition, expected longevity of the product, and the advantages or drawbacks of patent and trade secret regimes contribute to the inventor's decision to keep her invention a secret. While most of these factors are beyond the control of patent administrators, the inventor may also actively avoid the help of the patent system. However, this article is concerned with the converse situation where the inventor actively seeks patent protection (by applying for a patent) but is forced to resort to secrecy because the patent system, due to inefficient patent policies, denies protection to her otherwise technically meritorious invention. This article contends that the current utility standard under Manson is a prime example of such inefficient policy. n69 By adopting a more sensible approach to the utility standard, it is possible to encourage early disclosure and thus reduce or even eliminate the rent loss from secrecy that the patent system itself engenders. Conversely, though the rent dissipation at the conception and improvement stages can never be eliminated completely, it can be minimized because this rent loss is due to the inevitable competition for the market enjoyed by a successful product, with or without a patent system. Encouraging early disclosure is the essence, and thus should be the goal, of an efficient patent system.

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III. Utility of Pharmaceutical Products and Biotechnological Research Intermediates

"We have never received a clear answer to the question useful to whom and for what?" n70

It is noteworthy that economists, though interested in the study of utility and efficiency of social arrangements, have not sufficiently focused their attention on the utility requirement in the patent law. While utility is explicitly required in the statute, n71 it plays an equally important role in analyzing priority, n72 nonobviousness n73 and infringement. n74 The importance of the utility concept in patent law will continue to grow into the future because it affects the patentability of expensive and complex inventions belonging to pharmaceutical and biotechnological industries. Many biotechnological products that are useful only as research tools are not patentable under the current standard. After almost two hundred years of case law, utility remains elusive with no precise definition.

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A. Brenner v. Manson n75 and its Doctrinal Difficulties n76

Justice Story in his oft-quoted opinion in Lowell v. Lewis (1817) n77 explained that "[a]ll that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word 'useful' therefore, is incorporated in the act in contradistinction to mischievous or immoral." n78 For several decades prior to the Supreme Court's decision in Brenner v. Manson (1966), n79 both the Patent Office and the courts were routinely granting patents to chemicals without questioning their utility. n80 Chemical compounds were considered to have utility per se. n81 However, in In re Bremner (1950), n82 the CCPA held that the application must assert "utility and an indication of the use or uses intended." n83 Perhaps having recognized that the Bremner standard was too restrictive, the CCPA reverted in In re Nelson (1960) n84 to the pre-Bremner standard. n85

The issue of utility of chemical compounds came up again in In re Manson (1964). n86 Manson claimed a process that produced a steroid

[*643] intermediate, but the same process was already patented by Ringold and Rosenkrantz. Manson sought to invoke an interference to establish priority under

102(g). The Patent Office rejected Manson's request because Manson failed to state the utility of the product produced by the process. The CCPA reversed the Patent Office, holding that the utility of a process is established if the process is shown to produce the product, and that it is unnecessary that the product so produced should have utility. n87 In accordance with Justice Story's view, the CCPA considered utility as a minimal threshold standard.

In reversing the CCPA, the Supreme Court held that a process is not patentable if it produces a product that has no known utility and that a product has no patentable utility if its only use is as an object of further scientific research. n88 This article addresses both aspects of the Manson holding: it argues that the practical utility standard is doctrinally unsound and economically inefficient, that research intermediates have patentable utility, and that product inventions should be patentable if they meet Justice Story's standard of minimal or potential benefit.

The Court in Manson considered several arguments in reaching its holding. Manson argued that denying patent protection to chemical intermediates encourages secrecy rather than disclosure. The Court however discounted Manson's "virtue of disclosure" n89 argument by noting that the present art of clever patent claim drafting reveals only "as little useful information as possible." n90 It also dismissed claims of secrecy as exaggeration because if the inventor does not know a use for the product, he has every incentive to disclose the compound to others who may find a use for it. n91

Next, the Court expressed skepticism that others would have any incentive to search for uses of an already patented product because the patentee controls the manufacture of the product. n92 However, the Court failed to consider that the reward of a process patent would be a sufficient

[*644] incentive for those who find new uses for old compounds. n93 Further, the patent law had been construed to encourage such research by exempting inventors who experiment from the coverage of the infringement doctrine. n94 Cross- licensing between the owner of the product patent and the owner of the use-patent offers another solution. n95 It is a rare and irrational person that refuses to find a use for his invention and refuses to profit by licensing his invention to another who owns a use-patent on his product.

The lack of motivation argument of the Manson majority implies that the present practice offers sufficient motivation to the patentee to discover the highest and best use of his product. However, this implication is questionable. Presently, the utility requirement issatisfied by disclosing any use, not necessarily the best use. When a patent is issued with only a trivial use n96 disclosed, competitors in the market place might erroneously assume that the patentee would normally disclose (and thus has disclosed) the best use and would not invest further in that invention to find other uses. This lack of competition appears to encourage the patentee in turn not to invest in improving his invention further. n97 Merges and Nelson describe this problem of underdevelopment, or even total abandonment, of a patented product as "underfishing." n98 In this scenario, it is most likely that no one else other than the patentee himself finds the best use for the product. In the present system, even that likelihood is reduced because disclosure of the best use of a product is

[*645] not required for patentability. n99 Put differently, the present system does not provide enough motivation to others to invest in finding new uses for a patented compound.

On the other hand, when a product is allowed to be patented without disclosing a practical use, many inventors may compete to improve upon (find the practical or even best use for) that product. Merges and Nelson argue that competition at the improvement stage is desirable. n100 Competition to find uses for the new product certainly causes some rent dissipation, but such rent dissipation may be acceptable. "Indeed, . . . competition in the market for improvements is a value- creating, not value-depleting activity." n101 Moreover, competition to find uses for a disclosed product may not turn out to be rent dissipation at all. As discussed supra, n102 rent dissipation is most severe when the solutions to be found are limited. When a new chemical product is disclosed, the potential to find many different uses and thus possible solutions can be vast. Such a scenario may solve the underfishing problem, result in a fuller exploitation of the product, and lead to the further enrichment of the art.

The Court however offered "a more compelling consideration" for denying Manson's request.

Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of the monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting the monopoly

[*646] is the benefit derived by the public from an invention with substantial utility. n103

As Professor Chisum put it, this "'consideration' is far from 'compelling.'" n104 It is not the case that the metes and bounds of product or process claims are limited by their disclosed uses, unless a specific use is recited as part of the claim language. Moreover, "the 'metes and bounds' of the monopoly are never fully known at the time a patent issues - even when it discloses some specific and substantial utility." n105 Even if Manson's process or the compounds produced from it were to engross a vast area as feared, a reasonable solution is to reduce the scope of the claims to ones commensurate with the disclosure, rather than declaring that an entire class of compounds known as chemical intermediates are unpatentable if their sole utility is for further research. n106

It is possible that some inventors patent their inventions solely to block others from improving upon their products. However, this danger already exists in the current patent system. Because the current law does not require that the applicant disclose the highest and best use for a product to be patented, the applicant need only disclose any plausible legitimate use - not an insurmountable task to the inventors that seek patents for the sole purpose of blocking off future progress. n107

How does the society benefit from a product with trivial use (i.e., a product with its highest and best use unknown) any more than a product with no "practical" use? n108 Logically, the primary purpose behind granting a patent to a product with trivial use, instead of requiring that the inventor must disclose the highest and best use for his product, appears to facilitate early disclosure of that product to those in the art so that others may be able to find the highest and best use for that product, even many years later. Perhaps the idea is that, with respect to a product patent, making a product is the invention, and that once the society knows how

[*647] to make a product, it can eventually discover the highest and best use for that product. This argument for early disclosure of a product is reinforced by the existence of the statutory scheme that grants a patent to those inventors that find a new use to an old product or process. n109

However, the same argument can also be made in case of products with no known "practical" use, i.e., granting patents to such products promotes early disclosure to the same extent.

The Court's reasoning in Manson also raises the fundamental question of whether the utility standard should function as the gate-keeper to prevent the issuance of patents with broad scope. It would be hard to imagine that the Court was totally oblivious to the fact that research intermediates are valuable for the artisan while having commercial utility as well in the sense that they are being bought and sold. The Court, primarily concerned with the problem of preventing patents of broad scope rather than fine-tuning the doctrine of patent scope, chose the blunt-instrument of "practical utility." Thus, the distorted meaning given by Manson to utility arises from doctrinal confusion and has no firm basis either in the statute or in the case law. n110 It is unfortunate that the Supreme Court has taken that view and that Congress has not acted to correct the problem. n111

B. Economic Analysis of Manson

1. The Reward Theory

The Court in Manson appeared to follow strictly the reward theory when it stated that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." n112 The Manson decision on its face appears to be justifiable because it may

[*648] be nonsensical to grant patents that are useless to the society. n113 However, this argument begs the questions of "[u]seful to whom and for what?" n114 In a competition-oriented society, a product's value and best use is reflected ultimately in the product's commercial success. That the patent office is not in the best position to predict the practical utility of every invention is evident from the fact that of the thousands of patents issued each year, only a fraction of them are commercially successful.

Perhaps acknowledging this difficulty, courts have repeatedly stated that a showing of commercial utility is not required to satisfy

101. n115 But the question remains: where to fix practical utility on a utility scale with one end represented by research utility and the other end by commercial utility. The problem with Brenner v. Manson is that its standard is very close to, if not identical to, requiring a showing of commercial utility. It should be noted that the majority of the Supreme Court concluded the Manson opinion by approvingly quoting In Re Ruschig, n116 for the proposition that "a patent system must be related to the world of commerce rather than to the realm of philosophy." n117 The problem however is that objective proof of commercial success, the kind of evidence readily available in infringment cases, is lacking in many interference cases and in almost all cases of patent prosecutions. n118

Manson's focus on commercial utility to determine patent grant reflects a misunderstanding of how the patent system promotes progress in useful arts.

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The patent system does not promote progress merely by rewarding those who succeed commercially. It promotes it by stimulating inventive activity, by bringing about a disclosure of the results of that activity, and by encouraging investment in the production and marketing of inventions as well as in research and development. n119

On the other hand, it is conceivable that the Court was not actually looking for commercial utility because it is hard to imagine that the Court failed to notice that Manson's intermediates were not totally useless in the commercial sense. As Judge Rich in his dissent in In Re Kirk implied, steroids were valuable for researchers in that field, who might be willing to pay for such chemicals. n120 As a practical matter, a visit to a chemical research laboratory will show catalogs from several chemical companies filled with lists of chemical intermediates for sale. The Manson holding is simply a reflection of the Court's concern that the quid pro quo was not met, which, if true, would mean simply that the Court failed to notice the patent law solution of reducing the claim scope.

The quid pro quo argument is unconvincing for another reason. Because the patent grant is a means, not a guarantee, to achieve commercial gains, the basic quid pro quo is best determined by the market place, not by the patent office. An inventor creates his own reward, which is directly dependent on the invention's contribution to the society. n121 The patent office is not best suited to predict the practical utility of an invention because, as Merges concluded, such practical utility is determined by market forces that may be unrelated to the true technical merits of the invention. n122 Further, such prediction is riskier to make at the patentability stage because less information is available about the product as well as about the market's expectations or reactions. As Judge Rich expressed:

Patent applications must as a rule be made and examined soon after the invention is made. At this stage who can tell whether an invention is better? . . . Many are the inventions which cannot be tried out except by putting them on the market and which nobody will risk putting on the market unless there is patent protection. . . . The sort of commercial success, evidence of which is produced in infringement suits, which may demonstrate that an invention is better, occurs only after the invention has proved itself in the market place. Such evidence is not in existence at the patenting stage except in unusual cases. This is a cogent reason why the patent issuing agency should not have the power to pass on the question of relative superiority or to demand evidence of it as a prerequisite to patentability. n123

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By focusing on an invention's immediate benefit to the public, which benefit is difficult to measure accurately at the patenting stage, the Court ignored the invention's true technical merit (nonobviousness) and thus the invention's contribution to the progress of the art. This result is hardly conducive to encourage disclosure and promote the progress of the useful art concerned.

To do the job of promoting progress, the incentives afforded by patent protection have to be maintained to the point where they will encourage production, even of things that patent office examiners may think are inferior. They could be wrong and the inventor should have his chance. The marketplace will pass judgment. If that judgment goes against the patentee, as it frequently does, even with respect to inventions which look good to the patent office, there has been no loss to the public. It is difficult to understand the attitude of those who feel that ideally a patent should be granted only for the meritorious invention which is capable of being a commercial success. Patents are not Nobel or Pulitzer prizes! They are not for exceptional inventors but for average inventors and should not be made hard to get. True, they are temporary monopolies, but therein alone lies their power as inducements to invent, to disclose, to invest, and to design around. Why must an invention be a commercially hot number to be patentable? If it is a total dud, how is the public injured by a patent on it? A monopoly on something nobody wants is pretty much of a nullity. That is one of the beauties of the patent system. The reward is measured automatically by the popularity of the contribution. n124

Manson allows the patent office to substitute its own judgment for that of the market place as to the value of a patent to the society and thus interferes with the ultimate quid pro quo contemplated by the Constitution. The Manson holding is a misapplication of the reward theory.

2. The Patent-Induced Theory

The patent-induced theory suggests that only those inventions that would not have been developed but for the lure of a patent should be protected. n125 Thus inventions developed due to market pressures, or scientific curiosity, or by accident need not be protected because they would be disclosed to the public anyway. n126 While the soundness of these assumptions is questioned above, n127 this theory does not appear to support the Manson holding. It is unclear what motivated Manson to make those compounds. But it appears that Manson would not have disclosed his invention but for the expected patent protection. There was no indication

[*651] that he made the products due to market pressure. His research was not published, thus scientific curiosity probably was not the motivation. There was no question that Manson did not make his compounds by accident. Thus, Manson's invention should have been protected according to the patent-induced theory.

3. The Prospect Theory

The prospect theory states that the patent owner performs a supervisory function to the extent she controls through her patent monopoly all future improvements. n128 Competitors that wish to improve upon the patent need to get a license from the owner and thus they may avoid investing resources needlessly. Because an intermediate can potentially control many future developments, the claimant has greater power to coordinate future work. This avoids significant rent dissipation at the improvement stage. Accordingly, Manson should have been awarded his request under the prospect theory.

4. The Race-to-Invent Theory

According to Merges and Nelson, the proponents of the race-to-invent theory, allowing "broader claims of a small number of patents, primarily those on pioneering breakthroughs" n129 would slow down technological innovation. n130 It is most likely that Manson's process or its compounds were not breakthrough discoveries. One of Manson's compounds belonged to a class of steroids that has been published in the Journal of Organic Chemistry and they were being screened for possible anti-tumor activity. n131 In addition, Manson pointed out that a homologue of his compound was proven to be an anti-tumor compound. n132 The race-to-invent theory should allow patent protection to Manson's compounds. Further, the race-to-invent theory suggests that there would be rapid development if there is rivalry in the development stages. n133 Because a chemical intermediate can facilitate such rapid development of next

[*652] generation compounds, Manson deserved an interference request according to the race- to-invent theory.

5. The Rent Dissipation Theory

Grady and Alexander claim that the rent dissipation theory explains the result in Manson more convincingly. n134 According to that theory, a court needs some indication of commercial value to "balance patent rent against avoided rent dissipation." n135 The authors imply that the Court in Manson found no commercial value for Manson's compounds, thus Manson's compounds were not patentable. n136 However, the implication that Manson's compounds had no commercial value defies common knowledge in chemical research. Besides, the Court's primary concern, though appearing to be that of commercial value, was actually that Manson was claiming too much. n137

Further, Grady and Alexander's attempt to rationalize Manson is unconvincing. The rent dissipation theory holds that "[m]ost likely to receive patent protection are inventions that, although of comparatively small value, nonetheless signal a large potential for improvement." n138 On the other hand, "[e]xtremely valuable inventions, are only patentable if their signals for improvement are correspondingly large." n139 Regardless of the value of Manson's compounds, his process and the products deserved a patent because, as chemical intermediates, by very definition, they can signal many future compounds.

6. Summary of Doctrinal and Economic Analysis of Manson

Based on economic theories, and in light of established patent policies, Manson is ill-conceived, doctrinally unsound, and contrary to practical experiences in chemical research. Manson promotes economic

[*653] inefficiency and arbitrarily discriminates against research intermediates. n140 Perhaps recognizing the problems with Manson, the Federal Circuit appears to have softened the practical utility requirement. The more recent decisions of Cross v. Iizuka n141 and In Re Brana n142 illustrate this trend and thus require a closer analysis.

C. The Cross and Brana Decisions

Cross v. Iizuka n143 involved an interference concerning invention of thromboxane synthetase inhibitors, which are considered to be useful in treating inflammation, asthma, hypertension and other ailments. n144 After noting that practical utility is controlled by Manson, the court relied on Nelson v. Bowler n145 for the proposition that adequate proof of pharmacological activity satisfies the Manson standard. n146 Further, the court in Cross relied on Rey-Bellet v. Engelhardt n147 for the proposition that structural similarity to known pharmacologically active compounds can establish utility. n148 Thus, the Cross court held that Iizuka established practical utility because the parent Japanese application Iizuka relied on for priority disclosed same pharmacological activity for structurally related compounds. n149

The Cross court next addressed the far more important question of whether in vitro data is sufficient to show practical utility, because Iizuka did not show any in vivo data, either in his parent Japanese application or in his U.S. application. The court held that "under appropriate circumstances," in vitro testing may establish a practical utility for a pharmaceutical compound. n150 The appropriate circumstances include existence of a reasonable (not rigorous) correlation between the disclosed in vitro utility and an in vivo activity, "where the disclosure of pharmacological activity is reasonable based upon the probative evidence." n151

[*654] Such probative evidence includes uncontradicted "in vitro and in vivo pharmacological activity of structurally similar compounds." n152

In In Re Brana, n153 the CAFC again addressed the question of what constitutes practical utility of a pharmaceutical invention. n154 Brana's application was rejected under

112 for failing to disclose how to use the invention. n155 The board argued that Brana's assertions such as "treatment of diseases" and "antitumor substances" were not specific enough to survive the practical utility standard of Manson. The court rejected this argument on the fact that Brana's application disclosed that Brana's compounds had "a better action and a better action spectrum as antitumor substances" than known reference compounds. n156 Such "favorable comparison implicitly asserts that their claimed compounds are highly effective (i.e., useful) against lymphocytic leukemia. An alleged use against this particular type of cancer is much more specific than the vaguely intimated uses rejected [in Kirk]." n157

The court addressed the next contention that the tumor models do not represent specific diseases and that the artisan would not know against which specific disease Brana's compounds were directed. n158 This argument implies that the knowledge attributed to the artisan is not indicative of current scientific practices in the field of pharmaceutical research. n159 The cell lines Brana used, P338 and L1210, have been the

[*655] standard screens against lymphocytic leukemias for at least a decade prior to the Brana decision. n160 The court dismissed the board's argument rather quickly by pointing out that the tumor models were originally derived from lymphocytic leukemias in mice and thus represented specific diseases. n161

The Commissioner next argued, by citing to references that questioned the predictive value of in vivo murine tests of efficacy in humans, that the in vitro tests were inadequate to convince the artisan that the compounds are useful as antitumor agents. n162 The court stated that the artisan would not question the asserted utility of Brana's compounds because treating cancer with chemical compounds is not contrary to generally accepted scientific principles. n163 "In addition, the prior art discloses structurally similar compounds to those claimed by the applicant which have been proven in vivo to be effective as chemotherapeutic agents against various tumor models." n164

The Commissioner argued that the in vivo tests of the prior art are not reasonably predictive of success in humans because they are not clinical tests but only preliminary screening tests. The court responded that

proof of an alleged pharmaceutical property for a compound by statistically significant tests with standard experimental animals is sufficient to establish utility. . . . The Commissioner, as did the Board, confuses the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption. . . . FDA

[*656] approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. . . . Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. n165

The court stated that requiring clinical results would work hardship on many researchers and many potential cures may not be pursued. n166

Brana raises several interesting questions. First, in light of Cross as precedent, why did the court in Brana entertain the questions of whether the cell lines represented a specific disease and whether there was sufficient in vivo to human correlation? It should be noted that both in Cross and in Brana, the compounds in question were structurally related to prior art compounds whose pharmacological activity is beyond question. In both cases, there was no controversy as to the reliability of structural similarity to predict the stated pharmacological activity of the claimed compounds. The in vitro tests in both cases were standard tests. Thus, Brana presented the "appropriate circumstances" mentioned in Cross to support a ruling in Brana's favor without the need for further analysis. n167 The court's disposition based on Cross would have had the virtues of reinforcing Cross and avoiding the murky discussion relating to in vivo animal to human correlation.

Next, how broad is the statement that "[u]sefulness in patent law . . . necessarily includes the expectation of further research?" Is the court acknowledging indirectly that Manson was incorrectly decided? Does it mean that research intermediates are patentable? Is the court relaxing the standard for pharmaceuticals only? Considering that pharmacologic activity is a type of chemical property and, that under the Papesch n168 doctrine, "a chemical and all of its properties are inseparable[,]

[*657] they are one and the same thing," n169 is there a valid justification for treating chemical intermediates any differently from pharmaceuticals?

D. The Utility Standard for Pharmaceutical Products

Conceptually, there appears to be three major areas of objections the Patent Office can raise with regard to the utility of pharmaceutical products: those related to the specificity of the asserted utility; those related to the in vitro testing; and those related to the in vivo testing. The specificity question also leads to a rejection for failing to meet the enablement requirement of

112. n170 Specificity was the problem in In Re Kirk, n171 where the utility asserted was "biological activity." However, from Cross and Brana, it appears that the specificity problem can be overcome by carefully stating in the patent application the specific in vivo or in vitro pharmacologic activity displayed by the claimed compounds.

As to the in vitro and in vivo data, Cross and Brana are welcome relief for inventors of pharmaceuticals because the court no longer requires clinical data in all cases. However, in practice, Brana's applicability may be much limited because for many pharmacological classes of drugs, especially in certain therapeutically important cases such as AIDS, the correlation between animal and human studies is not well established. n172 Does Cross apply in those cases? n173 Cross applies only to those cases where a reasonable correlation between in vitro and in vivo data exists. Thus, where in vitro to in vivo animals correlation is not established, either because of the nature of the disease or because the treatment is a breakthrough (pioneering), Manson controls; i.e., the

[*658] inventor must show clinical data to show utility. As a result, "this higher standard of utility for pharmaceuticals . . . seems to live on as a practical matter. . . ." n174 This article contends that the requirement of such correlation is unnecessary, causes significant rent dissipation, and its implementation remains subjective at the Patent Office.

In vivo activity is an important piece of information that allows one to assess whether further testing, perhaps Phase I clinical studies, are warranted. However, as to establishing a practical utility in the Manson sense, the in vivo studies do not add much because any "practical utility" of a pharmaceutical is to be determined solely by the Food and Drug Administration ("FDA"). n175 If the FDA concludes that a compound is not safe and effective in humans, n176 the compound's practical utility (and its commercial viability) as a drug becomes nonexistent. Put differently, a compound with established correlation between in vitro and in vivo animals or even between in vivo animals and humans is no better off than a compound that has only been tested against suitable in vitro models so far as the FDA approval is concerned. FDA approval is notpredicated upon such correlation. The questions then become what purpose do the in vivo studies as required under Brana or Cross serve and whether those cases, particularly Brana, represent a significant step away from Manson. n177

Thus, the irony is that, in the case of pharmaceuticals, what is useful according to Brana may lack any practical utility in the real world if the FDA declares that the patented compound is not safe and effective for human treatment. This situation is exactly opposite to that in Manson where the Court held that chemical intermediates with potential commercial and practical value are useless in the patent law sense. In both situations, the law produces a result that defies common experiences of those in the art. Perhaps a better solution would be to allow applications based on standard in vitro data alone. As the Federal Circuit in Cross v. Iizuka n178 noted, "[i]n vitro testing, in general, is relatively less

[*659] complex, less time consuming, and less expensive than in vivo testing." n179 The PTO's current practice reminds one of its earlier practice, which has been abandoned after much repeated admonition by the Federal Circuit and its predecessor. The earlier practice insisted that a pharmaceutical product has no utility unless its safety has been established. n180

A further concern for the patent bar is that the Patent Office's adaptation of Brana appears to be less than enthusiastic and thus brings uncertainty. While the Federal Circuit has articulated the Brana standard in terms of reasonable question to the artisan, the Patent Office has formulated the standard in terms of "credible utility." n181 Even though the Examiner Guidelines state that the credible standard is met when "one of ordinary skill in the art would consider the assertions of the applicant to have any reasonable scientific basis," n182 Perryman and Setty argue that the Patent Office's choice of the word "credible" may indicate its intent to follow the higher standard of convincing evidence set by the CCPA precedents. n183 It would help applicants at large if the Patent Office published from time to time what tests it considers to have met the "reasonable scientific basis" standard. Such a pro-active step may avoid the subjectivity that exists in determining the level of understanding of the artisan. n184

Similar to many other research-oriented inventions, pharmaceuticals can be "useful" to the scientific community long before they are useful to the public at large. By knowing what drugs have been synthesized and what drugs have been screened, those in the art can modify their search accordingly and avoid rent dissipation at both the conception stage and latent stage. The Brana standard causes significant rent dissipation

[*660] because the inventor withholds disclosure while experimenting to produce the required data on correlation.

E. The Utility Standard for Biotechnology Products and Research Intermediates

The issue of whether patents should be granted to DNA or other biotechnological products that have no known "practical" use other than being useful for research purposes remains contentious. n185 Expressed Sequence Tags ("ESTs") and cDNAs n186 can be used in research in a number of ways: as probes to isolate coding sequences and complete genes; as chromosome markers; as diagnostic tools to detect the presence of a complementary mRNA in a certain tissue or species; and as regulators of gene expression through triple helix formation or antisense methods. n187 Many such uses make an EST or a cDNA a "research intermediate" in biotechnology. n188 Even though the cDNAs identified by the ESTs can be translated into highly valuable proteins, Manson dictates that unless one finds a specific use in presently available form for that protein, neither the protein, nor the cDNA, nor the EST is patentable and they are merely objects of scientific curiosity. n189

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The general consensus however is that research intermediates in biotechnology should be protected. As a practical matter, "[a]voidance of patents on research tools ignores the fact that research itself is an industry. If we wish to promote progress in such a field of endeavor, chemical compounds, which are in fact useful to research chemists in their work and commercial in the sense that they are manufactured, sold, and purchased for that purpose, should be provided protection. It is inherently easier to purchase a research chemical than to expend the time and energy necessary to manufacture it yourself." n190 The analogy to biotechnology is self-evident.

Moreover, biotechnology products represent a huge industry that is built on making and selling research products. The issue becomes, as Professors Eisenberg and Merges put it, whether "the existence of a commercial market among researchers confer[s] patentable utility on research reagents." n191 The policy argument that genetic research should be protected because it is big business is valid; however, so might have been the case with steroid chemical research at the time of Manson. n192

One major fear for allowing patents on biotechnology research intermediates is that such patents would block off future research areas. However, one wonders if this adverse consequence is merely fear or real. It is worth considering in this context the analogy made by Judge Rich that research intermediates are like scientific tools or equipment such as a spectrophotometer or an electron microscope. n193 What meaningful distinction can be made between these scientific research tools and the biotechnology research intermediates in terms of their capacity to hinder or help progress in the arts?

Professor Eisenberg pointed out that one concern about granting patents on research tools lies in the area of licensing. n194 The patent holder may chose to grant exclusive licenses only or she may coerce the

[*662] licensee/competitor to disclose the future direction of their research. n195 The argument is that if multiple licenses are needed, the difficulties and transaction costs also multiply. n196 While these are valid practical issues, these problems are inherent whenever an important discovery is made in a growing field of scientific research. For example, the same arguments could be made against patenting electron microscopes and spectrophotometers. As to the feared licensing behavior by the patentee, it is not unique to the biotechnology area; rather, it is related to the market power the patent confers, which power in turn is more related to the scope of the patent than its utility. n197 On the other hand, is it not the essence (and the beauty) of the reward notion inherent in the patent system n198 that the inventor of an important discovery be entitled to all the economic gain in the open market?

From an economic perspective, it makes sense to grant patents to biotechnology products and research intermediates because more information about those inventions can be disclosed earlier than otherwise possible. Moreover, there can be healthy competition to find uses for those proteins with unknown uses, n199 again accelerating information flow into the public domain. One may argue that such granting of patents causes significant rent dissipation at the conception stage itself. n200 However, as discussed supra, n201 this rent dissipation may be more than offset by the decreased rent dissipation at the latent stage. Even if the rent dissipation cannot be offset, there are strong policy arguments in favor of encouraging the race to find more DNA sequences and the proteins they encode.

One such policy argument is that a relaxed standard helps many inventors, including small biotech companies, who are not in a position to conduct additional tests to show the needed practical utility. n202 Faced with the need for additional capital to apply for a patent and the reality

[*663] that additional funds may not be forthcoming from investors unless one has a patent on hand, it is unlikely that many small companies will persist to the next stage. n203 The inventor would have to sell his invention, usually for a cheap price due to his weak bargaining position, to someone who can conduct the additional tests. In any case, the invention would be held up for a longer time in secrecy, causing substantially more rent dissipation, than if a relaxed utility standard is employed. Or worse, the inventor simply chooses to discontinue, in which case, the information may never be disclosed, an even greater loss to the society. Either scenario can chill further inventive endeavor at small firms and among entrepreneurs, n204 causing research to be concentrated at the big industrial firms that have the necessary resources to conduct all the experiments needed. n205

An effective solution is, rather, to narrow the scope of the product claim to what has been disclosed only. Dr. Chambers concludes that "the focus of the intellectual property community and scientific community should not be on the utility of the ESTs, but instead it should be on the breadth of any issued claims." n206 For example, by using the reverse doctrine of equivalents, n207 it is possible to confine the scope of

[*664] ESTs claimed so that other ESTs to be discovered and used as probes to the same cDNA can remain patentable. n208 Because the EST is a much shorter fragment than the cDNA, it cannot usually produce an active protein, whereas the much longer cDNA would usually be ineffective as a probe or a marker, a situation within the reach of the reverse doctrine of equivalents. n209 While the reverse doctrine of equivalents reduces the original inventors' monopoly, such loss is "outweighed by the encouragement of improvements which are themselves more valuable than the original." n210

One argument against patenting DNA inventions is that because they cannot be kept secret, they will eventually be disclosed to the public at practically no cost and thus patenting them is economically inefficient. Moreover, the rush to find certain DNA, such as a breast cancer susceptibility gene, causes significant rent dissipation at the conception stage. n211 It should be noted however that "it is far from clear that all rent dissipation is bad," n212 because some "goods" such as human life are priceless. The real question then is can the society afford to rely on market factors or accidents and wait for someone to disclose the invention, however long that might take? By offering patent protection, the law in fact encourages not only the making of such inventions but more importantly their early disclosure. The monopoly is in a sense a "premium" the society is willing to pay for expediting the disclosure. A rational society is amply justified in not wanting to wait for disclosures that can potentially save lives. When put in policy terms, the premium for earlier disclosure is the real issue in the debate about DNA patenting,

[*665] not whether someone is claiming too much or too little or has a right in the first place to claim any DNA at all. n213

IV. Perspectives

Several provisions in the patent statute signify that one major theme in patent law is to encourage early disclosure. n214 Early disclosure promotes economic efficiency n215 by minimizing rent dissipation that occurs when an otherwise completed invention is prevented from being disclosed by inefficient patent policies. This article argued that the Manson utility standard is a source of significant rent dissipation. Even worse, the present practice has encouraged some inventors to concoct uses that the inventors never intended (and the society may never wish) for the product. n216 This practice is misleading, economically inefficient, and should not be encouraged.

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Some commentators have suggested that making a product and using it are two distinct inventions n217 even though in many instances the two inventions may coalesce into one. Recognizing that using can be temporally distanced from the making of a product, the statute allows later inventors of new uses for old products to obtain a patent for that use. n218 Why then should the statute require that making the product be disclosed simultaneously with at least one of its "practical uses" in order to obtain a patent? The most likely reason for this rule is the lurking fear that if the inventor is not compelled to find and disclose a use, no other (later) inventor would expend resources to discover the uses of an already patented product. While this fear is rational, the present practice based on manipulating the plain meaning of "utility" is not only without statutory basis, n219 but also can be counterproductive in the long run.

As discussed supra, n220 in terms of benefits to the society, a product with trivial use may not be superior to a product with no "practical" use. Thus, if a product with trivial use can be patented under the current practice, why not allow a product that satisfies the minimal use standard of Justice Story? The metes and bounds argument of Manson is unconvincing because the danger of claiming unknown areas of future progress exists even under the current system. n221 The Manson argument of lack of incentive to discover new uses by others has less force. n222 First, contrary to the implication in Manson, the current practice does not provide any greater incentive to the patentee to discover the highest and best use for his product. n223

In addition, while the lack of incentive argument might have had some appeal at Manson's time, today the argument is less persuasive. The case of Dawson Chemical v. Rohm & Haas Co., n224 together with the statutory right to a patent under

101, appear to provide sufficient incentive to other inventors who find new uses to already disclosed products. The Supreme Court in Dawson Chemical held that the later

[*667] inventor who found a use for the chemical propanil n225 could enforce the use patent even though such enforcement resulted in monopolizing a product that had been in the public domain for six decades prior to the patent, n226 and that such enforcement activity was within the ambit of

271(d), which is not a patent misuse or antitrust violation. n227 Perhaps Dawson Chemical is an ideal example to illustrate the power conferred by

101 and

271(d) on the inventor (and thus the incentives to other inventors) of a new use to effectively monopolize the product. n228

Thus, a better solution to the "practical utility" problem of research intermediates is to limit the patent scope, not to deny patent protection to this important class of products. n229 One legislative solution is to establish a bright line by overruling Manson, either returning to Justice Story's formulation or declaring altogether that certain products

[*668] have utility per se. n230 The notion that certain inventions can have utility per se is not new. n231 More recently, Professor Oddi recommends that inventions with high investment but no established market value should be patentable without ha ving to establish practical utility. n232 In addition, it is noteworthy that the European utility standard based on whether an invention is "susceptible of industrial application" n233 is very close to that of Justice Story's minimal utility standard. "Industrial application" apparently includes utility in pure research. n234

The per se utility rule clearly promotes early disclosure of compounds and thus significantly reduces rent dissipation both at the conception stage and at the latent stage. n235 Moreover, the rule creates beneficial competition at the improvement (finding uses) stage. n236 From the inventor's point of view, early disclosure makes sense: as the original inventor of the product, she has the head start and more knowledge of the product and thus is more likely to win the race to find the best use.

[*669] Delaying disclosure until she finds the best use may result in loss of priority to another. n237

Patenting a product based on the minimal utility standard of Justice Story would also bring symmetry to patent law. Currently, a

102 prior art reference need not disclose any utility to anticipate the claimed invention. In In Re Hafner, n238 the CCPA held that even though Hafner's German application was not effective to enable his U.S. application because it did not disclose any use (because such disclosure was not required under the German law), that German application anticipated the compound in his U.S. application. n239 How can the utility requirement be dispensed with in the case of prior art references but not in the context of a patent application? n240 In writing the opinion, Judge Rich expressed his inability to rationalize the holding other than to state that the current law demanded the result. n241

One may argue that liberalizing or overruling the Manson standard may flood the patent system with useless patents and dilute the value of patents. This argument assumes that the current system does not issue patents that are found to be invalid later. However, this assumption is not entirely true. Courts have historically invalidated a large percentage of patents that were challenged. During 1921 through 1973, district courts invalidated 55% of the patents challenged and the courts of appeals invalidated 65%. n242 Of those patents issued between 1948 through 1977, district courts held roughly 52% of the challenged

[*670] patents to be obvious, while 64% were found to be obvious by the courts of appeals. At the Patent Office, in 1984, about 10% of the patents were canceled upon reexamination. n243 While the numbers appear to have decreased after the advent of the Federal Circuit, perhaps due to increased uniformity in interpretation, a significant number of patents continue to be invalidated by the courts. n244

V. Summary

Encouraging early disclosure is one of the major themes of the patent system. By using rent dissipation as a criterion, this article demonstrates that early disclosure decreases rent dissipation at various stages of invention and is thus economically efficient. The "practical utility" standard of Manson discourages early disclosure, incorrectly focuses on the patent grant as the ultimate reward, and places the responsibility of judging the value of an invention on the patent office, a job to which the patent office is not best suited. Instead, the patent grant should be considered as a means to the ultimate reward of commercial gain and the valuation should be left to the marketplace.

This article argues that Manson has distorted the meaning of "utility" and ascribed to the utility doctrine the role of a gate-keeper to prevent issuance of patents of broad scope. The Manson opinion reflects a fundamental misunderstanding of the policy of promoting the progress in useful arts. Its focus on promoting useful articles, to the exclusion of the technical merits of the invention, is shortsighted. It is high time that the patent bar openly reject this much mutilated utility doctrine to bring economic sense and doctrinal coherence to the patent law and let true progress in useful arts continue.

The Brana standard is only a partial solution because it does not apply to non-pharmaceutical products and even when applicable, requires significant in vitro to in vivo correlation. Regardless of whether Brana or Manson controls, because of the particular regulatory scheme applicable to pharmaceuticals, the FDA has the final authority to pass on the "practical utility." Ironically, the FDA may find a product without

[*671] use (for human therapy) even though the Patent Office may declare that product to be useful. This article argued that rejecting pharmaceutical product inventions based on the Manson and Brana standards serves no meaningful objective of the patent system or the society at large.

On the other hand, Manson prevents many biotechnology products such as cDNAs, ESTs, and proteins from becoming patented because many such products, though highly valuable to the artisan and to the progress of the art, function solely as research intermediates. The fear that patenting biotechnology research intermediates grants a monopoly on unknown and vast areas offuture research is exaggerated and unwarranted. Denying patents to these valuable inventions is contrary to the objective of promoting progress.

n1 "Congress shall have the power to . . . promote the Progress of the useful Arts, by securing for limited times to . . . inventors the exclusive right to their respective . . . discoveries." U.S. Constitution Art. I 8 cl. 8. This clause is commonly known as the patent clause. The purpose of the patent system that originated from the patent clause is to promote progress in the useful arts, and, contrary to the common misconception, it is not concerned with progress in science, as science was understood to mean literature during the time of framing the Constitution. See Giles S. Rich, The Principles of Patentability, *42 J. Pat. Off. Soc'y 75, 77-80 (1960).*

n2 *23 U.S.P.Q.2d (BNA) 1334* (Bd. Pat. App. & Int'f. 1992).

n3 *Id. at 1339.*

n4 *383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).*

n5 *Id. at 534-35, 148 U.S.P.Q. (BNA) at 695.*

n6 "Whoever invents or discovers any new and useful process, machine, manufacture, composition of matter, or any new and useful improvement thereof, may obtain a patent therefor . . . " *35 U.S.C. 101.*

n7 *Manson, 383 U.S. at 535, 148 U.S.P.Q. (BNA) at 695-96.*

n8 In the remote corners of the most crowded arts, progress is made by the proliferation of ideas, different and unobvious ways of doing the same thing, so that the reservoir of inventions fills up. It should never be forgotten that patented inventions are published and become a part of the technical literature. This publication itself promotes progress in the useful arts . . . . Whenever novel subject matter, unobvious to the workers of ordinary skill in an art, is published, progress in the art is promoted. The literature of the art is enriched, another way of doing something is made known . . . There is no telling when it may give another inventor an idea or when someone will improve on it in such a way as to surpass all that is known. Everyone can learn from mistakes, including the mistakes of others, provided he can find out about them. Patents on inventions that have failed can promote progress. Abandoned applications cannot. Rich, supra note 1 at 83.

n9 Kenneth D. Sibley, Practical Utility: Evolution Suspended?, 32 IDEA 203, 205 (1992).

n10 See generally, Elizabeth A. Hall, The Impact of a Weakened Patent Policy on Development Incentives, 31 Q. Rev. Econ. & Bus. 79 (1991), for an elaborate argument that inefficient patent policies can impede innovation.

n11 Letter from Kate H. Murashige, Chairwoman, Biotechnology Committee, Am. Intell. Prop. L. Ass'n, October 27, 1997. The letter reports that at the annual meeting of October 16-18, 1997, Group Director John Doll of the PTO was puzzled "over the decline in filing in the biotech area; the total is only about 50% of expectations." As stated in the text, a causal connection is difficult to establish between this decline in the number of patent applications in biotechnology and the current utility and other patentability standards. However, it is noteworthy that the overall investment in biotechnology by the venture capital industry has increased from about $ 412 million in 1995 to about $ 645 million in 1996, an increase of about 60%. See Seth Fineberg, It's in the Way that You Use it: VCs Hone their Strategies as Investment Levels Soar, Venture Capital Journal, 42, 44, July 1997. Unless there is a significant lag from the time of investment to the time of filing a patent application, this statistic suggests that lack of funds may not be the sole reason for the slow-down in filing biotechnology patent applications.

n12 *753 F.2d 1040, 224 U.S.P.Q. (BNA) 739 (Fed. Cir. 1985).*

n13 *51 F.3d 1560, 34 U.S.P.Q.2d (BNA) 1436 (Fed. Cir. 1995).*

n14 See infra Part III C.

n15 A. Samuel Oddi, Un-Unified Economic Theories of Patents--The Not-Quite-Holy Grail, *71 Notre Dame L.Rev. 267, 271 (1996)* [hereinafter Oddi, Un-Unified Economic Theories].

n16 Some recent reviews include: Mark A. Lemley, The Economics of Improvement in Intellectual Property Law, *75 Tex. L. Rev. 989 (1997);* Oddi, Un-Unified Economic Theories, supra note 15; Matthew Erramouspe, Comment, Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races, *43 UCLA L. Rev. 961 (1996);* J. Miles Hanisee, Comment, An Economic View of Innovation and Property Right Protection in the Expanded Regulatory State, *21 Pepp. L. Rev. 127 (1994);* Yusing Ko, Note, An Economic Analysis of Biotechnology Patent Protection, *102 Yale L. J. 777 (1992);* Mark F. Grady and Jay I. Alexander, Patent Law and Rent Dissipation, *78 Va. L. Rev. 305 (1992);* Donald L. Martin, Comment, Reducing Anticipated Rewards From Innovation Through Patents: or Less is More? *78 Va. L. Rev. 351 (1992);* Robert P. Merges, Comment, Rent Control in the Patent District: Observations on the Grady-Alexander Thesis, *78 Va. L. Rev. 359 (1992)* [hereinafter Merges, Rent Control]; Robert P. Merges and Richard R. Nelson, On the Complex Economics of Patent Scope, *90 Colum. L. Rev. 839 (1990);* A. Samuel Oddi, A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit: Beyond Obviousness: Invention Protection in the Twenty-First Century, *38 Am. U. L. Rev. 1097 (1989)* [hereinafter Oddi, Twenty-First Century]; Robert P. Merges, Commercial Success and Patent Standards: Economic Perspectives on Innovation, *76 Calif. L. Rev. 805 (1988)* [hereinafter Merges, Commercial Success].

n17 Grady and Alexander, supra note 16 at 309 (stating that rent-dissipation theory explains the outcome of many past cases).

n18 Oddi, Un-Unified Economic Theories, supra note 15 at 271.

n19 *383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).*

n20 Professor Oddi has summarized the costs as those associated with: under-utilization of the protected invention; avoiding the protected invention--'inventing around;' blocking alternative solutions - blocking or defensive patents; over-investing in applied as compared to basic research; increased difficulty of making inventions in heavily patent- protected fields; administering a patent system; and abusing the patent monopoly. See Oddi, Twenty-First Century, supra note 16 at 1111-12.

n21 See generally, Fritz Machlup, Study of the Subcomittee on Patents, Trademarks and Copyrights of the Senate Judiciary Committee, 85th Cong.; An Economic Review of the Patent System, Study No. 15 (Comm. Print 1958); C. Freeman, The Economics of Idustrial Innovation (2d ed. 1980); F. M. Scherr, Innovation and Growth: Schumpterian Perspectives (1984); Ward S. Bowman, Jr., Patent and Antitrust Law: A Legal and Economic Appraisal (1973); Edmund W. Kitch, The Nature and Function of the Patent System, *20 J.L. & Econ. 265 (1977).*

n22 For a recent account of the interesting aspects of the origin of the patent clause, see Edward C. Walterscheid, To Promote the Progress of Science and Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution, 2 J. Intell. Prop. L. 1 (1994). Professor Walterscheid points out that the patent clause "is unique in being the only instance wherein the delegates [to the Constitutional Convention] prescribed a specific mode of accomplishing the particular authority granted." Id. at 33. "That the delegates should include the particular method is interesting because there are a variety of ways of promoting the progress of science and the useful arts which have nothing whatever to do with the granting of exclusive rights for limited times in writings and inventions or discoveries." Id. The variety of ways "that had already been attempted by the time of the Constitutional Convention were medals, honorary titles, premiums, bounties, and other rewards of various types." Id. at n.108. While fully cognizant of the evils of monopolistic behavior, "the delegates' reason was purely a pragmatic one," that is, the patent monopoly "would cost the federal government the least to implement." Id. at 34.

n23 William F. Baxter, Legal Restrictions on Exploitation of the Patent Monopoly: An Economic Analysis, *76 Yale L.J. 267, 268-69 (1966).*

n24 See generally, Richard R. Nelson, The Economics of Invention: A Survey of the Literature, 32 J. Bus. 101 (1959).

n25 "In 1785, Jeremy Bentham, comparing rewards by bonus payments with rewards by 'exclusive privileges,' took the view that the latter approach was 'the best proportioned, the most natural, and the least burdensome' in that it produces an infinite effect and costs nothing." Walterscheid, supra note 22 at 35 n.112 (citations omitted).

n26 Id. at n.111, quoting Klaus Boehm & Aubrey Silberston, The British Patent System 1 (1967).

n27 Ward S. Bowman, Jr., Patent and Antitrust Law: A Legal and Economic Appraisal (1973).

n28 That the patent monopoly is a means, rather than a guarantee, is evident from the fact that the public will not buy a product merely because it is patented. Commentators have criticized the reward theory as being unable to account for the inequality in the patent system in that one inventor may earn vast sums for making a trivial investment in labor and monies whereas others may earn only small returns even though they have labored hard and invested heavily. See Edith T. Penrose, The Economics of the International Patent System, 30-31 (1951). However, this criticism is unfair. From the notion that the market place is the ultimate venue where the rewarding takes place, it is clear that it is up to the inventor to make the decision of whether to invest in the invention by carefully considering, among other factors, the potential for success in the market place.

n29 See infra Parts III A and B for the argument that Manson involved such a misunderstanding.

n30 For example, the reward theory does not explain why some inventions that are very useful to the society, such as the Post-It note pads of 3M, are denied a patent. The reward theory also fails to explain why discoveries of natural phenomena or scientific principles cannot be protected under the patent system even though they lead to breakthrough discoveries. See Penrose, supra note 28 at 29-30. In some cases, a patent reward is unnecessary because the inventor has the "head-start" and the market advantages of being the first will suffice as an incentive. F. Scherr, Industrial Market Structure and Economic Performance, 443-50 (2d ed. 1980).

n31 Grady and Alexander, supra note 16 at 313.

n32 Oddi, Twenty-First Century, supra note 16 at 1113.

n33 The priority law, the doctrine of constructive reduction, and enablement standards reflect this principle. See *35 U.S.C. 102*(g) and 112.

n34 *35 U.S.C. 103*(a).

n35 Daniel L. McKay, Comment, Patent Law and Human Genome Research at the Crossroads: The Need for Congressional Action, 10 Computer & High Tech. L. J. 465, 491-92 (1994); David G. Perryman and Nagendra Setty, The Basis and Limits of the Patent and Trademark Office's Credible Utility Standard, 2 J. Intell. Prop. L. 509, 511 (1995).

n36 Oddi, Twenty-First Century, supra note 16 at 1110.

n37 The premium on early disclosure is reflected in many statutory provisions: 102(a-e), dealing with statutory bars that prevent the issuance of a patent for delay in making an invention or in applying for a patent, with the result that the invention would be lost to the public domain; 102(g), dealing with the issues of priority, where delays in filing or completing an invention, or misconduct such as suppression or concealment that leads to delays in disclosure, would result in loss of claim to another inventor.

n38 Oddi, Un-Unified Economic Theories, supra note 15 at 281.

n39 Kitch, supra note 21 at 266.

n40 Ko, supra note 16 at 803.

n41 Merges and Nelson, supra note 16 at 872.

n42 Id.

n43 "Rivalry no doubt causes waste. Yet we have little faith in the imagination and willingness of a 'prospect' holder to develop that prospect as energetically or creatively as she would when engaged in competition. We are also skeptical about her ability to orchestrate development. Given the way humans and organizations think and behave, we believe we are much better off with considerable rivalry in invention than with too little." Id. at 877.

n44 Ko, supra note 16 at 803.

n45 Merges and Nelson, supra note 16 at 878.

n46 Oddi, Un-Unified Economic Theories, supra note 15 at 283.

n47 Id.

n48 "The concept of rent in economics identifies returns over and above the costs required to get an economic good produced, or to keep it in production." Martin, supra note 16 at 351.

n49 Grady and Alexander, supra note 16 at 308.

n50 Id.

n51 Id.

n52 Id.

n53 Id. at 320.

n54 Id.

n55 Id. at 322.

n56 Oddi, Un-Unified Economic Theories, supra note 15 at 284-85. Perhaps the first criticism should be that Grady and Alexander employ imprecise terminology. It is unclear what an elegant invention means and how one defines "invention" and "improvement." Second, to illustrate their theory, Grady and Alexander chose poor examples and old cases, such as *Morton v. New York Eye Infirmary, 17 F. Cas. 879 (C.C. S.D. N.Y. 1862),* involving Dr. Morton's ether patent, that may not be relevant to contemporary patent law. "Explaining cases that are no longer good law comes perilously close to prescribing a normative theory, one which would change contemporary doctrines back to what it was under the older cases." Merges, Rent Control, supra note 16 at 367. "Grady and Alexander must tell the United States Supreme Court that it always gets the patent cases right--or at least, that it always has in the past. By explaining the pattern of past cases, they leave no room for the [courts] to change the law in accordance with future developments." Id. at 367-68. A more fundamental problem with the rent dissipation theory however lies in its application. In applying the theory, "how would we know when an invention signaled the possibility for improvements and when it did not? Grady and

Alexander give us no specific criteria and only a few examples." Martin, supra note 16 at 356. The most important reason for this difficulty appears to be the authors' failure to tell us what signal means.

n57 It is stressed here that, given the difficulties outlined above with respect to the rent dissipation theory, only the basic concept that rent dissipation occurs at different stages of the inventing process is accepted for the purposes of this article. In contrast to the prior attempts by others to rationalize the patent case law under one economic theory or another, this article, taking rent dissipation as a criterion of economic (in)efficiency, evaluates how the current standards of utility and priority affect rent dissipation. The analysis will be used to suggest adjustments in interpreting current standards so that greater economic efficiency can be realized from the patent system.

n58 Merges, Rent Control, supra note 16 at 359.

n59 Every competitive situation necessarily involves expenditure of resources that are redundant to a certain extent. Market conditions determine whether a given situation is rent dissipation or healthy competition. Consider the example of two rival grocers across the street from each other, selling a given product at identical prices. Is this desirable competition or is it a waste of resources and thus rent dissipation? It depends on additional factors. With only one grocer in the town, there is a strong tendency for him to be monopolistic. Conversely, if the business demand is just enough to provide a reasonable return to only one store, then having the additional store would be considered rent dissipation.

n60 See infra notes 113-120 and accompanying text for the discussion on Manson's focus on commercial value of an invention.

n61 Grady and Alexander, supra note 16 at 308-09.

n62 "Even without a patent system, there will always be some rent dissipation, for the market induces competitive investments." Oddi, Un-Unified Economic Theories, supra note 15 at 285.

n63 *35 U.S.C. 101*.

n64 See infra notes 96-102 and accompanying text.

n65 Grady and Alexander, supra note 16 at 308-09.

n66 Grady and Alexander mentioned only this type of rent dissipation. Id.

n67 Inventors often have to weigh the advantages of relying on patent law as opposed to trade secret law in order to protect their inventions. The choice is often governed by the nature of the invention, competition, expected market power the invention brings (and thus the revenues to be generated), strategic concerns, as well as the advantages and disadvantages inherent of each regime, among others. The patent system, from an idealistic point of view, is aimed at reducing or even eliminating trade secrets. However, it is unrealistic to expect that the patent system provides enough incentive to do away with trade secret protection entirely. For the sake of simplicity, this discussion assumes the situation where the inventor could opt for either patent or trade secret protection.

n68 The enablement, written description and best mode requirements of *35 U.S.C. 112* will ensure that that the invention has been described in enough detail for the artisan to practice.

n69 See infra Part III A and B.

n70 *In re Nelson, 280 F.2d 172, 126 U.S.P.Q. (BNA) 242 (C.C.P.A 1960).*

n71 *35 U.S.C. 101.*

n72 Priority is concerned with that aspect of the patent law that determines who among two or more competing inventors of a given subject matter should win the contest.

n73 Nonobviousness, put in lay terms, measures the technical merits of an invention. The nonobviousness doctrine is codified in 103(a) of the patent statute. In the chemical context, utility affects the nonobviousness determination in at least two ways: (1) in establishing a prima facie case of obviousness; and (2) in rebutting the prima facie case. The CAFC held that a prima facie case of obviousness is made when the prior art discloses compounds that are structurally related to the claimed compounds and the prior art also provides motivation (by disclosing utility for the prior art compounds). *In re Dillon, 919 F.2d 688, 692, 16 U.S.P.Q. (BNA)2d* (BNA) 1897, 1901 (Fed. Cir. 1990) (en banc). The applicant can rebut the prima facie case by showing that the claimed compounds possessed unexpected properties (and hence unexpected utility). See *In re Eli Lilly & Co., 902 F.2d 943, 948, 14 U.S.P.Q. (BNA)2d* (BNA) 1741, 1744 (Fed. Cir. 1990).

n74 In infringement litigation, the defendant often raises the defense of invalidity of the patent for lack of utility of the invention. This argument is rejected by many courts as being specious simply because the claim arose due to the defendant using the invention for his own gain. Perhaps, as suggested by Professor Chisum, a better formulation of this defense is that the patentee has not disclosed how to use the invention and thus failed to meet 112 enablement standard. Donald S. Chisum, Patents, 4.04.

n75 *383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).*

n76 The Manson decision provoked considerable reaction. For an in-depth judicial criticism, see *In re Kirk 376 F.2d 936, 947, 153 U.S.P.Q. (BNA) 48, 266 (C.C.P.A. 1967)* (Rich, J. dissenting) and *In re Jolly, 376 F.2d 906, 909, 153 U.S.P.Q. (BNA) 45, 243 (C.C.P.A. 1967)* (Smith, J. dissenting). For a sample of the reaction from the patent bar, see Eric P. Mirabel, "Practical Utility" is a Useless Concept, *36 Amer. U. L. Rev. 811 (1987);* Harold S. Meyer, Utility Requirement in the Statute, *49 J. Pat. Off. Soc'y, 533 (1967);* David A. Anderson and Edward E. Dyson, Comment: Some Special Problems with the Utility Requirement in Chemical Patents, *35 Geo. Wash. L. Rev. 809 (1967);* Comment: Patentability of Chemical Intermediates, *56 Cal. L. Rev. 497 (1968);* Iver Cooper, Patent Problems for Chemical Researchers - the Utility Requirement after Brenner v. Manson, 18 IDEA 23 (1976); Lawrence. R. Velvel, A Critique of Brenner v. Manson, *49 J. Pat. Off. Soc'y, 5 (1967);* Paul H. Eggert, Uses, New Uses and Chemical Patents - A Proposal, *51 J. Pat. Off. Soc'y, 768 (1969).*

n77 *15 F. Cas. 1018 (C.C.D. Mass. 1817).*

n78 *Id. at 1019.*

n79 *383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).*

n80 *Id. at 539, 148 U.S.P.Q. (BNA) at 697* (Harlan, J., dissenting).

n81 *Kirk, 367 F.2d at 950-51, 153 U.S.P.Q. (BNA) at 270* (Rich, J., dissenting).

n82 *182 F.2d 216, 86 U.S.P.Q. (BNA) 74 (C.C.P.A. 1950).*

n83 *Id. at 217, 86 U.S.P.Q. (BNA) at 75.*

n84 *280 F.2d 172, 126 U.S.P.Q. (BNA) 242 (C.C.P.A. 1960).*

n85 Id. at 283, 126 U.S.P.Q. (BNA) at 252.

n86 *333 F.2d 234, 142 U.S.P.Q. (BNA) 35 (C.C.P.A. 1964).*

n87 *Id. at 236, 142 U.S.P.Q. (BNA) at 36.*

n88 *Manson, 383 U.S. at 535, 148 U.S.P.Q. (BNA) at 696.*

n89 *Id. at 534, 148 U.S.P.Q. (BNA) at 695.*

n90 Id.

n91 Id.

n92 Id.

n93 See e.g., *35 U.S.C. 101;* Chisum, supra note 74 at 4.02[2][c][]; Velvel, supra note 76 at 8. See infra notes 224-28 and accompanying text for the argument that 101 and 271(d) and the Supreme Court's ruling in *Dawson Chemical Co. v. Rohm & Haas Co., 448 U.S. 176, 206 U.S.P.Q. (BNA) 385 (1980)* weaken Manson's lack of incentive argument.

n94 *Kirk, 376 F.2d, at 965, n.7, 153 U.S.P.Q. (BNA) at 281, n.7* (Rich, J., dissenting); Chisum, supra note 74 4.02[2][c][]; Cooper, supra note 76 at 28.

n95 Cooper, supra note 76 at 28.

n96 The term trivial use as used in this article refers to the use that is not the highest and best use for that product.

n97 Merges, Rent Control, supra note 16 at 372- 73, n. 52-54. Other reasons include satisfaction in the status quo of commercial advantage offered by the product patent, underestimation of the potential demand for a new item, neglect of the inventor, misdirection of research, incompatible goals of the management and the innovator, and reluctance to expend valuable resources in further research of unknown potential. Id. at 371-72.

n98 Merges and Nelson, supra note 16 at 873-74; Merges, Rent Control, supra note 16 at 371.

n99 It is not intended here to criticize this rule of not having to disclose the highest and best use for a product for its patentability. It appears that such is a sensible rule because the highest and best use of a product may not be known for several years, and conceivably in many cases may be found by someone other than the original inventor of the product. A rule that requires the disclosure of the highest and best use causes delays in disclosure and defeats the patent system's major objective of early disclosure.

n100 "Our general conclusion is that multiple and competitive sources of invention are socially preferable to a structure where there is only one or a few sources. Public policy, including patent law, ought to encourage inventive rivalry, and not hinder it. As the 'race to invent' models show, a rivalrous structure surely has its inefficiencies. But such a structure does tend to generate rapid technical progress and seems a much better social bet than a regime where only one or a few organizations control the development of any given technology." Merges and Nelson, supra note 16 at 908.

n101 Merges, Rent Control, supra note 16 at 375.

n102 See supra notes 62-64 and accompanying text.

n103 *Manson, 383 U.S. at 534, 148 U.S.P.Q. (BNA) at 695.*

n104 Chisum, supra note 74 at 4.02 [2][c][ii].

n105 Id.

n106 See e.g., Scott A. Chambers, Comments on the Patentability of Certain Inventions Associated With the Identification of Partial cDNA Sequences, 23 Am. Intell. Prop. L. Ass'n Q.J., 53, 59 (1995).

n107 See *Kirk, 376 F.2d at 960-61, 153 U.S.P.Q. (BNA) at 277* (Rich, J., dissenting). For an illustration of how an inventor concocted "legal utility" see infra note 216 and accompanying text.

n108 "There is no practical difference in the promotion of the useful arts between inventions with no known use and those with a mere nominal use." Salim A. Hasan, A Call for Reconsideration of the Strict Utility Standard in Chemical Patent Practice, 9 High Tech. L. J. 245, 263 (1994).

n109 See *35 U.S.C. 101.*

n110 The Court's apparent attempt to look to the legislative history for guidance was misplaced. As Judge Rich argued, the legislature during the 1953 codification of the patent statute left the case law of over a century and a half undisturbed with the intent that prior meaning of utility should continue. *Kirk, 376 F.2d at 954, 153 U.S.P.Q. (BNA) at 272* (Rich, J. dissenting).

n111 *Id. at 957, 153 U.S.P.Q. (BNA) at 274-75;* Several commentators have argued for congressional action to overrule Manson or to clarify the law by adopting a "clear" definition of utility. See generally, Meyer, supra note 76 at 543; Velvel, supra note 76 at 13; McKay, supra note 35 at 494-95; G. Kenneth Smith and Denise M. Kettelberger, Patents and the Human Genome Project, 22 Am. Intell. Prop. L. Ass'n Q.J. 27, 60- 63 (1994).

n112 *Manson, 383 U.S. at 536, 148 U.S.P.Q. (BNA) at 696.*

n113 The counterargument is that if a patented subject matter has no use to the society, what has the society lost by granting a patent? This argument that even useless inventions may be granted patents was implicit in Justice Story's reasoning. *Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568)* ("If [an invention] be not extensively useful, it will silently sink into contempt and disregard."). See also, Rich,

supra note 1 at 85 ("If [an invention] is a total dud, how is the public injured by a patent on it?).

n114 *Nelson, 280 F.2d at 80, 126 U.S.P.Q. (BNA) at 250.*

n115 See *In Re Anthony, 414 F.2d 1383, 1396, 162 U.S.P.Q. (BNA) 594, 605 (C.C.P.A. 1969)* (holding that commercial usefulness "has never been a prerequisite for a reduction to practice and the subsequent patentability of any of the classes of patentable subject matter set forth in section 101, much less the particular class of compositions of matter called drugs."); *In Re Langer, 503 F.2d 1380, 1393, 183 U.S.P.Q. (BNA) 288, 298 (C.C.P.A. 1974)* ("development of a product to the extent that it is presently commercially salable in the market place is not required to establish 'usefulness' within the meaning of 101.").

n116 *343 F. 2d 965, 145 U.S.P.Q. (BNA) 274 (C.C.P.A. 1965).*

n117 *Manson, 383 U.S. at 536, 148 U.S.P.Q. (BNA) at 696.*

n118 Rich, supra note 1 at 84 ("Such evidence [of commercial success] is not in existence at the patenting stage except in unusual cases.").

n119 Id. at 83-84.

n120 *Kirk, 376 F.2d at 957, 153 U.S.P.Q. (BNA) at 274* (Rich, J, dissenting).

n121 Supra note 24-29 and accompanying text.

n122 See generally, Merges, Commercial Success, supra note 16.

n123 Rich, supra note 1 at 84.

n124 Id. at 84-85.

n125 See supra note 38 and accompanying text.

n126 See supra note 32 and accompanying text.

n127 See supra note 35 and accompanying text.

n128 See supra note 39 and accompanying text.

n129 Merges and Nelson, supra note 16 at 916.

n130 Id.

n131 *Manson, 383 U.S. at 522, 148 U.S.P.Q. (BNA) at 690.*

n132 Id.

n133 Merges and Nelson, supra note 16 at 877.

n134 Grady and Alexander, supra note 16 at 339.

n135 Id.

n136 "Brenner is therefore consistent with rent dissipation theory in that a court must know something about an invention's potential commercial applications in order to balance patent rent against avoided rent dissipation" Id.

n137 See supra notes 108-111 and accompanying text.

n138 Grady and Alexander, supra note 16 at 320.

n139 Id. at 339.

n140 Oddi, Twenty-First Century, supra note 16 at 1127.

n141 *753 F.2d 1040, 224 U.S.P.Q. (BNA) 739 (Fed. Cir. 1985).*

n142 *51 F.3d 1560, 34 U.S.P.Q.2d (BNA) 1436 (Fed. Cir. 1995).*

n143 *753 F.2d 1040, 224 U.S.P.Q. (BNA) 739 (Fed. Cir. 1985).*

n144 *Id. at 1044, 224 U.S.P.Q. (BNA) at 743.*

n145 *626 F.2d 853, 206 U.S.P.Q. (BNA) 881 (C.C.P.A. 1980).*

n146 *Cross, 753 F.2d at 1046, 224 U.S.P.Q. (BNA) at 744.*

n147 *493 F.2d 1380, 181 U.S.P.Q. (BNA) 453 (C.C.P.A. 1974).*

n148 *Cross, 753 F.2d at 1049, 224 U.S.P.Q. (BNA) at 746-77.*

n149 *Id. at 1050, 224 U.S.P.Q. (BNA) at 746-47.*

n150 *Id. at 1051, 224 U.S.P.Q. (BNA) at 748.*

n151 *Id. at 1050, 224 U.S.P.Q. (BNA) at 747.*

n152 *Id. at 1051, 224 U.S.P.Q. (BNA) at 748.*

n153 *51 F.3d 1560, 34 U.S.P.Q.2d (BNA) 1436 (Fed. Cir. 1995).*

n154 The court stated that the issue was "not a new issue; it is one which we would have thought had been settled by case law years ago." *Id. at 1564.* The court's apparent exasperation is not without justification. As far back as 1986, the Board itself stated that "alleged cancer utilities can no longer be classified as 'incredible.'" *Ex parte Krepelka, 231 U.S.P.Q. (BNA) 746, 747* (Bd. Pat. App. &. Int'f. 1986).

n155 Brana's invention involved novel substituted benzodeisoquinoline-1,3-dione compounds claimed to possess antitumor activity.

n156 Id.

n157 Id.

n158 Id.

n159 The person having ordinary skill in the art (PHOSITA) has traditionally been interpreted to have varying levels of skill depending on the context in which such determination is made. For example, in the context of nonobviousness, PHOSITA is presumed to know subject matter published even in foreign language publications, regardless of how remotely accessible such publications are. On the other hand, the PHOSITA in the context of enablement is presumed to know only the most common and widely accessible subject matter. This differential treatment is justifiable to a certain extent for the policy reasons that an inventor should not capture what is already in the public domain (in the nonobviousness context) and that the public should not unduly experiment and search extensively to practice the invention (in the enablement context). However, in the case of utility, either extreme in the level of knowledge attributable to

PHOSITA appears unwarranted. For an interesting discussion on PHOSITA, see John O. Tresansky, PHOSITA The Ubiquitous and Enigmatic Person in Patent Law, 73 J. Pat. & Trademark Off. Soc'y 37 (1991).

n160 See generally Phanesh Koneru, Improvement of Antileukemic Activity of Hydroxyaminoguanidine Derivatives by Molecular Modification and Through Combination with Cytarabine against CCRF-CEM/0 Cells (1992) (Ph.D. Dissertation, University of Southern California).

n161 "If applicants were required to wait until an animal naturally developed this specific tumor before testing the effectiveness of a compound against the tumor in vivo, as would be implied from the commissioner's argument, there would be no effective way to test compounds in vivo on a large scale." *Brana, 51 F.3d at 1565, 34 U.S.P.Q.2d (BNA) at 1440.*

n162 *Id. at 1565-66, 34 U.S.P.Q.2d (BNA) at 1440- 41.*

n163 "The purpose of treating cancer with chemical compounds does not suggest an inherently unbelievable undertaking or involve implausible scientific principles." *Id. at 1566, 34 U.S.P.Q.2d (BNA) at 1441.*

n164 Id.

n165 *Id. at 1567* (emphasis added), *34 U.S.P.Q.2d (BNA) at 1442.*

n166 "Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer." *Id. at 1568, 34 U.S.P.Q.2d (BNA) at 1442-43.*

n167 In fact, Brana went one step beyond Iizuka and produced in vivo animal data, whereas in Cross, the court was satisfied with the expert evidence indicating that the artisan was aware that structurally related compounds were active in vivo. See *Id. at 1567, 34 U.S.P.Q.2d (BNA) at 1441; Cross, 753 F.2d at 1049, 224 U.S.P.Q. (BNA) at 746.* While the Brana court acknowledged that such in vivo data satisfies Brana's burden to prove that the artisan would have been convinced of the asserted utility, *Brana, 51 F.3d at 1567, 34 U.S.P.Q.2d (BNA) at 1441-42,* the court should have disposed off the case by citing to Cross at that point. Instead, by engaging in further analysis, the court created the perception that Brana and Cross, even though both were dealing with the general question of practical utility of pharmaceuticals, were somehow not related otherwise.

n168 *315 F.2d 381, 137 U.S.P.Q. (BNA) 43 (C.C.P.A. 1963).*

n169 *Id. at 391, 137 U.S.P.Q. (BNA) at 51.*

n170 See e.g., *Brana, 51 F.3d at 1564, 34 U.S.P.Q.2d (BNA) at 1439.*

n171 *376 F.2d 936, 941, 153 U.S.P.Q. (BNA) 48, 52 (C.C.P.A 1967).*

n172 See *Ex parte Balzarini, 21 U.S.P.Q.2d (BNA) 1892, 1895* (Bd. Pat. App. & Int'f. 1991) (the Board ruled that in vitro and in vivo correlation is not established for treating AIDS). It can be implied from the Brana opinion that such in vivo animal to human

correlation is important. The court, in answering the contention that Brana's in vivo animal studies were of questionable predictive value for human treatment, did not reject the argument or openly deny that such correlation is not needed. Instead, the court argued that one of the references questioning the predictive value was only concerned with lung cancer, as opposed to the leukemias in question, while the other reference had information to in fact weaken the Board's argument. *Brana, 51 F.3d at 1568, 34 U.S.P.Q.2d (BNA) at 1442.*

n173 See Sibley, supra note 9 at 220 n. 93 (1992) (stating that lack of correlation between in vivo animals and humans would be a problem).

n174 Rebecca S. Eisenberg and Robert P. Merges, Opinion Letter as to the Patentability of Certain Inventions Associated With the Identification of Partial cDNA Sequences, 23 Am. Intell. Prop. L. Ass'n Q.J. 1, 3, (1995).

n175 See generally, Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at *21 U.S.C. 301*-393 (1988)).

n176 Id. at 355(b)(1), (d) and (e).

n177 It could be argued that the in vivo studies are at least a start or are of some indication, however poorly might be the case, of potential use of the compounds as drugs. For that matter, such potential use could have been inferred in Manson as well. Oddi, Un-Unified Economic Theories, supra note 15 at 307.

n178 *753 F.2d 1040, 224 U.S.P.Q. (BNA) 739 (Fed. Cir. 1985).*

n179 *Id. at 1050, 224 U.S.P.Q. (BNA) at 747.*

n180 See *Anthony, 414 F.2d at 1395, 162 U.S.P.Q. (BNA) at 603-04; Brana, 51 F.3d 1567, 34 U.S.P.Q.2d (BNA) at 1442; Scott v. Finney, 34 F.3d 1058, 1063, 32 U.S.P.Q.2d (BNA) 115, 1120 (Fed. Cir. 1994).* In all of these cases, the court held that the issue of safety of a pharmaceutical should be left to the FDA's determination.

n181 The Patent and Trademark Office Examiner Guidelines for Examination of Applications for Compliance with the Utility Requirement, *60 Fed. Reg. 97 (1995).*

n182 Id. at Overview of Legal Precedent Governing the Utility Requirement, II. B.2.

n183 Perryman and Setty, supra note 35 at 529. However, the difference in terminology could be due to the lack of synchronization between the Brana decision and the release of the Guidelines. See Michelle L. Johnson, Comment, In Re Brana and the Utility Examination Guidelines: A Light at the End of the Tunnel? *49 Rutgers L. Rev. 285, 306 n. 142 (1996).*

n184 Timothy R. Howe, Comment, Patentability of Pioneering Pharmaceuticals: What's the Use? *32 San Diego L. Rev. 819, 830 n. 54 (1995).*

n185 The "utility" of biotechnological products, especially that of DNA sequences and fragments as well as proteins with unknown biological functions has been much debated. See generally, Stephen Maebius, Novel DNA Sequences and the Utility Requirement: the Human Genome Initiative, J. Pat. & Trademark Off. Soc'y, 651 (1992); Eisenberg and Merges, supra note 174; Chambers, supra note 106 at 59; McKay, supra note 35 at 485-88; Antoinette F. Konski, The Utility Rejection in Biotechnology and

Pharmaceutical Prosecution Practice, J. Pat. & Trademark Off. Soc'y, 821 (1994); Diana Sheiness, Patenting Gene Sequences, 78 J. Pat. & Trademark Off. Soc'y, 121 (1996).

n186 cDNAs are "copy" or complementary DNAs that are made from messenger RNAs isolated from specific tissue extracts by using an enzyme called reverse transcriptase. Reverse transcriptase is not made in human cells, but usually isolated from certain RNA viruses. cDNAs contain only the coding portions of the genomic DNA and thus are considered the "edited" versions of the genomic DNA and are much shorter to sequence. Expressed Sequence Tags (ESTs) are partial cDNA sequences, which are typically 150-400 base pairs in length are obtained by partially sequencing randomly selected clones from human cDNA libraries. See generally The Human Genome Project: Deciphering the Blueprint of Heredity, 137-150 (Necia G. Cooper ed., 1994); *In Re Deuel, 51 F.3d 1552, 34 U.S.P.Q.2d (BNA) 1210 (Fed. Cir. 1995).*

n187 Eisenberg and Merges, supra note 174 at 13- 14.

n188 Hasan, supra note 108 at 260.

n189 Id.; Christopher A. Michaels, Biotechnology and the Requirement for Utility in Patent Law, 76 J. Pat & Trademark Off. Soc'y 247, 258 (1994) ("[I]f the court follows the holdings of Brenner, Joly, and Kirk, the mere fact that the NIH cDNAs encode human proteins will not be enough. After all, NIH has not taught the public how to use the human proteins.").

n190 Chambers, supra note 106 at 54.

n191 Eisenberg and Merges, supra note 174 at 19.

n192 One solution is to try to apply the Brana standard to biotechnology product patents as well. However, Brana may not be applicable to all biotechnology products because many of the biotechnology intermediates such as ESTs, cDNAs, or DNA sequences or even many proteins do not have any known pharmacological properties and are at present used mostly as research intermediates.

n193 *Kirk, 376 F.2d at 961, 153 U.S.P.Q. (BNA) at 278.*

n194 Rebecca S. Eisenberg, Symposium: A Technology Policy Perspective on the NIH Gene Patenting Controversy, *55 U. Pitt. L. Rev. 633, 647 (1994).*

n195 Id.

n196 Id.

n197 It should be cautioned that a patent monopoly does not necessarily translate into market power. See e.g., Russell Lombardy, Comment, The Myth of Market Power: Why Market Power Should Not Be Presumed When Applying Antitrust Principles to the Analysis of Tying Agreements Involving Intellectual Property, *8 St. Thomas L. Rev. 449 (1996).*

n198 See supra notes 24-29 and accompanying text.

n199 See Merges and Nelson, supra note 16 at 908.

n200 Erramouspe, supra note 16 at 996 (arguing that the recent rush to find the breast cancer susceptibility gene is but one such example).

n201 See supra notes 67-69 and accompanying text.

n202 See Howe, supra note 184 at 854; Perryman and Setty, supra note 35 at 512-13.

n203 See Perryman & Setty, supra note 35 at 512- 13.

n204 Id. This "Catch-22" was discussed long time ago by Judge Rich, albeit in the context of chemical and other inventions. See Rich, supra note 1 at 84. ("Many are inventions which cannot be tried out except by putting them on the market and which nobody will risk putting on the market unless there is a patent protection.").

n205 See Howe, supra note 184 at 854 ("Thus, to avoid granting a monopoly to inventors who have made a de minimis showing of utility, the patent office has awarded a de facto monopoly to large companies who have made no showing at all.").

n206 See Chambers, supra note 106 at 59. For example, a cDNA or an EST can be patented as a marker element, apparently an object of research. If a later inventor goes to the trouble of isolating and sequencing the gene that is marked by the cDNA or the EST and then goes on to make the encoded protein, the original claim to the cDNA or EST should be interpreted narrowly to cover only what was disclosed. The doctrine of equivalents should not cover the later discovered protein because the cDNA and the EST do not function substantially similarly to an expression vector containing the coding DNA. Thus, the scope of the original claim can be narrowed. Id. at 58-59.

n207 See generally, *Scripps Clinic & Research Foundation v. Genentech Inc., 927 F.2d 1565, 18 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 1991); Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 805 F.2d 1558, 1563, 231 U.S.P.Q. (BNA) 833 (Fed. Cir. 1986), SRI International v. Matsushita Electric Corp., 775 F.2d 1107, 227 U.S.P.Q. (BNA) 577 (Fed. Cir. 1985),* for a discussion of the reverse doctrine of equivalents. The court in Matsushita articulated the doctrine as follows: "The law acknowledges that one may only appear to have appropriated the patented contribution, when a product precisely described in a patent claim is in fact 'so far changed in principle' that it performs in a substantially different way' and is therefore not an appropriation." *Matsushita, 775 F.2d at 123, 227 U.S.P.Q. (BNA) at 580* (emphasis original).

n208 See Michaels, supra note 189 at 259-60; Michael S. Greenfield, Note, Recombinant DNA Technology: A Science Struggling With the Patent Law, *44 Stan. L. Rev. 1051, 1078-79 (1992).*

n209 See Michaels, supra note 189 at 260.

n210 See Lemley, supra note 16 at 1065. Professor Lemley argues that the reverse doctrine of equivalents offers an incentive for inventors to invest in bringing out radical improvements, i.e., improvements that are significantly more valuable than the original invention. Id. Additionally, the doctrine offers a relief from the holdup problem where the original inventor would not license his invention to others or charges exorbitant fees for such licensing. Id. at 1067. Further discussion of the reverse doctrine of equivalents or its economic implications is beyond the scope of this article.

n211 Erramouspe, supra note 16 at 995-96.

n212 Merges, Rent Control, supra note 16 at 359.

n213 Perhaps this policy is best reflected in the holdings of *In Re Bell, 991 F.2d 781, 26 U.S.P.Q.2d (BNA) 1529 (Fed. Cir. 1993)* and *In Re Deuel, 51 F.3d 1552, 34 U.S.P.Q.2d (BNA) 1210 (Fed. Cir. 1995)*, where the CAFC held that DNA is a chemical, albeit a complex one, and that one must envision the exact sequence of, rather than a method to isolate, the DNA for conception. The flip-side of this holding is that DNA is nonobvious if the prior art has not disclosed the exact sequence. While there has been some criticism, this holding is justified on many grounds, including the policy argument mentioned in the main text. For a criticism of the Bell and Deuel holdings, see Philippe Ducor, The Federal Circuit and In Re Deuel: Does 103 Apply to Naturally Occurring DNA? 77 J. Pat. & Trademark Off. Soc'y 872 (1995); Anita Varma and David Abraham, DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market, 9 Harv. J. L. & Tech. 53 (1996).

n214 The statutory bars of 102(a), (b), (d), (e) and (g) encourage early disclosure. The interference law under 102(g) also encourages early disclosure while accommodating the notion of fairness to the one who invented first. In addition, it is a basic tenet of patent law that a person will not get a patent unless he files an application (and thus discloses) even if he was the first to invent.

n215 "All other things being equal, it probably is beneficial to give an incentive for firms to innovate as quickly as possible." Merges and Nelson, supra note 16 at 879.

n216 *Kirk, 376 F.2d at 960-61, 153 U.S.P.Q. (BNA) at 277* (Rich, J., dissenting). Judge Rich described two situations where the inventors had to concoct "legal utility." In one example, a carboxyl group on a chemical product was hydrolyzed and made into copper salt to produce a compound with antifungal activity solely to satisfy the Patent Office. In another example, a complex aromatic compound with benzene ring was sulfonated to produce a compound with surface-activity, even though the new compound would be too expensive ever to be used for that purpose. Id.

n217 See e.g., Eggert, supra note 76 at 784.

n218 *35 U.S.C. 101* (granting patent for "any new and useful improvement.").

n219 "There is not the least practical necessity nor statutory obligation, so far as I can determine, for insisting on inclusion in the patent of ['definite'] use information with respect to newly invented compounds." *Kirk, 376 F.2d at 961, 153 U.S.P.Q. (BNA) at 278* (Rich, J., dissenting).

n220 See supra notes 108-109 and accompanying text.

n221 See supra notes 106-108 and accompanying text.

n222 See supra note 92 and accompanying text.

n223 See supra notes 96-99 and accompanying text.

n224 *448 U.S. 176, 206 U.S.P.Q. (BNA) 385 (1980).*

n225 Propanil is a nonstaple chemical that has no use except through practice of the method patented by Rohm & Haas.

n226 *Id. at 213, 206 U.S.P.Q. (BNA) at 403.* Rohm & Haas, the respondent, patented a method for applying propanil as a herbicide to kill unwanted plant growth in rice fields.

Propanil was first patented as a product by Monsanto Co. in 1968. Approximately four years later, when Monsanto sued Rohm & Haas for infringement, Rohm & Haas challenged the validity of the patent. The district court invalidated the patent (and the 3rd Circuit affirmed) upon the finding that propanil was implicitly disclosed in prior art as far back as 1902. *Id. at 181-82, 206 U.S.P.Q. (BNA) at 390.*

n227 *35 U.S.C. 271*(d) provides that "[n]o patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse . . . by reason of his having . . . (3) sought to enforce his patent rights against infringement or contributory infringement." Rohm & Haas alleged that Dawson Chemical was liable as a contributory infringer by manufacturing and supplying the chemical propanil to farmers with directions to apply propanil, where the directions were in accordance with the method patented by Rohm & Haas. Dawson Chemical argued that allowing Rohm & Haas to enforce the patent would grant an illegal monopoly over a nonstaple article of commerce and that Rohm & Haas's refusal to license amounted to patent misuse. The Court, based on an extensive survey of congressional record, rejected these arguments and held that 271(d) authorizes patentees "a statutory right to control nonstaple goods that are capable only of infringing use in a patented invention, and that are essential to that invention's advance over prior art." *Id. at 213, 206 U.S.P.Q. (BNA) at 403.*

n228 It can be argued that, because Dawson Chemical involved a product that was in the public domain when the issue arose, Rohm & Haas's monopoly would have been only partial had there been a valid product patent at that time. While this argument is valid, it does not significantly affect the sufficiency of the incentive argument made in the text. As rational business parties, in that case, Rohm & Haas would have had to engage in licensing and cross-licensing. However, in Dawson Chemical, Rohm & Haas did not have to seek a license to manufacture, a situation that led to a complete monopoly by Rohm & Haas over the product. As a result, Rohm & Haas chose to exploit that monopoly to the fullest extent by refusing to license Dawson Chemical.

n229 See supra notes 206-207 and accompanying text.

n230 Most significantly, see Judge Rich's dissent in In Re Kirk calling for legislative action. "From the practical administrative standpoint, the best rule, which is what we had in substance until 1950, is that chemical compounds are per se 'useful' within the meaning of *35 U.S.C. 101. . . .* If this cannot be brought to pass by court decisions, then the problem should be submitted to Congress. An effective statute which would restore the law to what it was for a century and a half would merely have to provide: (a) that new and unobvious chemical compounds are per se useful within the meaning of *35 U.S.C. 101,* and (b) that it shall be conclusively presumed that chemists will know how to use them within the meaning of *35 U.S.C. 112." Kirk, 376 F.2d at 957, 153 U.S.P.Q. (BNA) at 275* (Rich, J., dissenting). See also, Velvel, supra note 76 at 13 ("Congress ought to conduct a searching investigation and, if the facts warrant, statutorily authorize the issuance of patents to inventors who have reasonable grounds to assert a likely research use and who meet the other statutory requirements."). See also Johnson, supra note 183 at 310-14, for the argument that biotechnology inventions should be considered useful per se.

n231 Prior to 1955, the courts and the PTO considered chemical products to have utility per se. *Manson, 383 U.S. at 539-40, 148 U.S.P.Q. (BNA) at 697* (Harlan, J., dissenting).

n232 Oddi, Twenty-First Century, supra note 16 at 1129.

n233 "European patent shall be granted for any inventions which are susceptible of industrial application, which are new, and which involve an inventive step." Article 52(1), the European Patent Convention, Oct. 5, 1973, *13 I.L.M. 268.*

n234 See Hasan, supra note 108 at 266, citing Stephen A. Bent, et al., Intellectual Property Rights in Biotechnology Worldwide 146 (1987).

n235 See supra note 230 and accompanying text.

n236 See supra notes 96-102 and accompanying text.

n237 Under the current law, an invention is not reduced to practice unless one finds a practical use for that product. *Scott v. Finney, 34 F.3d 1058, 32 U.S.P.Q.2d (BNA) 1115 (Fed. Cir. 1994).* Accordingly, the inventor who made the compound but not found a use for it would lose to another who made the compound later but found the use sooner.

n238 *410 F.2d 1403, 161 U.S.P.Q. (BNA) 783 (C.C.P.A. 1969).*

n239 *Id. at 1405, 161 U.S.P.Q. (BNA) at 786.*

n240 Hafner strongly implies that the invention in a chemical product patent is the actual chemical structure and a method of making it, and the use of the chemical can be less important. Obliquely, this implication also follows from the conclusion by Merges that commercial utility is not a reliable indicator of the true technical merit (nonobviousness) of the invention. Merges, Commercial Success, supra note 16 at 854-55. This observation supports the statement made earlier in the text that in case of product patents, making the product is nine tenths of the invention in many cases.

n241 "But for [Manson, Kirk and Joly] and their stringent requirements as to the kind of 'utility' which must be disclosed . . . , the writer [Judge Rich] personally would agree with [Hafner] that the disclosure of how to use in his parent application . . . complies with the statutory requirements . . . But the writer's personal views are not the law." *Hafner, 410 F.2d at 1406, n.8, 161 U.S.P.Q. (BNA) at 786, n.8.*

n242 Oddi, Twenty-First Century, supra note 16 at 1140 n. 241 (citations omitted).

n243 Id.

n244 See Donald R. Dunner, Introduction, 13 Am. Intell. Prop. L. Ass'n. Q. J. 185, 186 (1985) (presenting data and concluding that in 102 and 103 cases, the CAFC's rate of validation or invalidation is not biased toward the patentee and thus not significantly different from the validation rate of the district courts). See also Rochelle C. Dreyfuss, The Federal Circuit: A Case Study in Specialized Courts, *64 N.Y.U.L. Rev. 1, 26-30 (1989)* (arguing that the CAFC "is a fairly balanced court," Id. at 29).