Why it is time to eliminate genomic patents, together with natural extracts doctrine that have supported such patents

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Abstract

The constitutional purpose of intellectual property is to "promote the progress of science and useful arts." Given the utilitarian basis of patents, it is critical that policies and laws must be continually adjusted to reflect the needs of new technologies. When the law tries to shield itself from rather than confront the realities of underlying technologies, patents end up actually subverting rather than promote technological progress. This paper explores why the natural extracts doctrine belongs to the class of doctrines that subvert progress. The doctrine, established over a century ago to enable the patenting of purified compounds for use as drugs, represent codification of old, outdated science, by allowing genes to be patented. While this paper does not give a whole scale solution regarding the policies that best incentivize biotechnological innovations, it does show how the natural extracts doctrine and the genetic patents it has spawned can impede innovations in the biotechnological context. It ends by offering a glimpse of how eliminating the natural extracts doctrine can remove not only some of unnecessary wrinkles in current patent law but more importantly the many current and future patent shackles to biotechnological innovations.

I) Introduction

As science and technology play increasingly vital roles in society, laws and policies designed to promote their advancements have come under increasing scrutiny. The ever-rising stakes have spurred increasingly bitter debates over how best to incentivize innovations.[1] U.S. patent law features a property-based system for incentvizing innovation.[2] Property based intellectual property (IP) systems, however, present double-edged swords.[3] As long understood, even as patents spur innovations, they also cause underutilization of those innovations and even disincentivization of follow-on innovations.[4]

Many technologists see the 21st century as the century of biotechnology. However, today's biotechnology industry is at a critical crossroad. Despite the industry's impressive progress over the last three or so decades and the consensus that patents have played and will continue to play an important role in promoting the development of the industry, there is fear also that patent practices in biotechnology have gotten out of control and are spurring current economic activities at tomorrow's expenses. The *Scripps* and *Amgen* recombinant technology cases (featuring disputes over biomolectular extraction technologies)[5] showcased how patents that incentivized innovations in one era may actually end up blocking innovations in a subsequent era. Since genomics patents touch upon far more technologies than purification innovations, the *Scripps* and *Amgen* cases importantly foreshadowed how serious the cost of blocking patents in the genetics context can be.

This paper addresses the problems of overly broad patents in biotechnology. Specifically, it addresses why the practice of patenting genes can be counterproductive to the development of the biotechnological field. The paper traces the legal foundation of genetic and other broad biotech patents to an obscure legal doctrine heretofore referred to as the *natural extracts doctrine*, whereby extracts obtained from nature, even if unmodified in molecular structure, are deemed patentable if the extracted substance (in bulk form) provides some novel therapeutic properties despite the fundamental prohibition against the patenting of nature. This doctrine, together with the Chakrabarty case, has opened a floodgate of biotechnological patenting activities. The Federal Circuit has tried to stem the patent floodtide by creating new doctrines such as a modified written specifications requirement. However, by failing to acknowledge the natural extracts doctrine, which systematically create overly broad patents through a construction of patentable "manufacture" ungrounded in technological reality, as the real culprit underlying biotech's patenting floodgate, the court has thus far not met much success. Broad patents are especially harmful in science-based industries where innovations take place in multiple rounds such as biotech, as early patents interfere with latter patents to stymie subsequent follow-on innovations. The paper presents an economics framework for understanding such harms. By introducing an economic framework for understanding patents and applying the framework in a way that is informed by insights into the nature of biotechnological innovations today, the paper recommends that the *natural extracts doctrine*, together with the broad patents it has spawned, be promptly and decisively abandoned.

II) General Sense of Unease

The impressive rise of the American biotechnology sector has been nothing short of amazing.[6] Since the creation of the first genetically engineered organisms in 1973,[7] the industry has grown into a critical, multi-billion dollar industry.[8] Many have cited the availability of strong patents as key to the U.S. success, [9] which some of observed as enabling and incentivizing the private sector to carry out more and more of the industry's R&D.[10] But despite the apparent importance of patents, there is also a general unease at the current explosion of patenting activity.[11] As the number of applications skyrocketed and scope of subject matter exploded, some have questioned whether the issuance of broad fundamental patnets might be incentivizing current innovations at the expense of the future progress.[12] Biotechnology is a field where innovations take place in multiple rounds.[13] The ultimate benefit of a breakthrough is often not available until several rounds into the innovation life cycle when combined with multiple subsequent innovations.[14] For example, while the sequencing of a gene by itself may be exciting, much still need to be discovered and invented before life-enhancing applications become a reality.[15] The ultimate applications will come when knowledge generated from those genes will allow doctors to diagnose and treat currently uncurable diseases. If too much patents incentives are awarded too early in the innovation life cycle today, little incentives may be available to drive the rest of innovations needed to create those ultimate applications tomorrow.[16]

A) Controversy over Genetic Patents

i) An issue of number and scope

As of 1999, the USPTO has awarded nearly 3,000 patents related to human genes (that's about 10% about the estimated 30,000 – 40,000 genes that exist in the human genome).[17] Craig Venter made news when he filed 6,500 provisional patent applications over human genes in October 1999.[18] To some, the increase in patent applications reflects innovations in the area;[19] to others, the increase reflects merely legal bickering and squatter.[20]

Gene patents are especially problematic because of their broad scopes. Today's gene patents cover much more than just the nucleotide structure and amino acid sequences (though even that would be problematic[21]), but also potential derived products and uses. For example, many EST[22] applications claim not just the isolated sequences, but also the use of the genes for diagnostic purposes; the use of the genes as tools in genetic research; the use of the genes in gene regulation applications such as antisense and triple helix applications; even all sequences located by the disclosed EST.[23] It is not uncommon for one to claim "not only the specific ESTs that had actually been identified and sequenced, but also complementary sequences, allelic variations and portions thereof, full genes corresponding or hybridizing to any of the foregoing sequences, fragments of such full genes, vectors containing any such sequences or genes, panels of ESTS or sequence fragments, and antisense oligonucleotides or triple helix probes capable of blocking expression of the products of the full genes."[24] Patent number 6,093,809 (issued July 25, 2000) is a prototypical broad gene patent. The patent is directed not just at the nucleic acids and amino acids of telomerase, an enzyme imputed in the aging and cancer

mechanisms, but also all "related" DNA sequences; all drugs derived from the protein coded by the sequence; the use of the sequences in genetic studies; and all pharmacological compositions that could be envisioned at the time.[25]

In general, it has become questionable whether patent incentives are really appropriate for genes[26] when sequencing has become increasingly routine and automated and would most likely continue unabated even without patent incentives.[27] Today, the status of gene patents remains uncertain.[28] Even as the U.S.P.T.O. has officially pronounced genes to be patentable subject matter, the P.T.O. has also allowed a very long backlog of patent applications to build up.[29] Fearing the harm such patents can cause to future research, some in the private sector have taken the problem into their own hands. Ten prominent pharmaceutical companies, for example, have joined to form a consortium called the Wellcome Trust. The goal is to patent a collection of SNPs[30] only to disavow them, legally preventing others from patenting a library of SNPs.[31]

ii) Fundamental disagreement over the effectiveness of gene patents to incentivize innovations in biotech

The disagreement over genetic patents is reminiscent of recent controversies over other expansions of patentable subject matter such as those to software and business methods. However, on closer examination, the gene patent controversy is also very different.[32] The primary concern about software and business methods patents related to patent quality. The PTO, which bases most of its prior art research on the patent literature, issued many patents of questionable quality because it did it not possess a library of patents that adequately reflected the prior art. As the prior art patents have built up, however, so seemingly have the uproar over software and business patents. The controversies over gene patent, on the other hand, are driven in addition by fundamental disagreements over the effect of patents.[33] As this paper will argue, any novelty derived from gene research today involves the actual extraction and/or application of genetic sequences, not the gene sequences by themselves. The sequences have existed in the natural human body, passing from generations to generations, since time immortality. While some believe that gene product patents [gene patents, for short] are necessary and proper for driving innovation in biotech, many others believe that that gene patents create unnecessary costs of innovations.[34]

B) Scripps and Amgen's Recombinant DNA Cases

Two high profile biotechnology cases in the late 1980's demonstrate the threats broad patents can pose to long-term technological progress. In *Scripps Clinic and Research Foundation v. Genentech, Inc.*, patentee Scripps sued Genentech over Genentech's effort to commercialize recombinant Factor VIII:C.[35] Factor VIII:C is a naturally occurring protein found in the human body essential to blood clotting, and the purified form was a leading drug candidate to treat hereditary bleeding disorders such as hemophilia.[36] Scripps had previous isolated Factor VIII:C from human blood plasma from large sources of blood and obtained a patent over purified Factor VIII:C.[37] Because of the inefficiencies involved in Scripp's analog purification techniques, it was not until Genentech's recombinant DNA techniques that Factor VIII:C began to hold out real commercial promise.[38] To the dismay of many, the courts held that Genentech's

recombinantly produced Factor VIII:C infringed Scripp's original patent over monoclonal-derived Factor VIII:C.[39]

In *Amgen, Inc. v. Chugai Pharmaceutical Co.*, Amgen sued, among other reasons, to declare that its efforts to commercialize recombinant erythropoietin (EPO)[40] did not infringe United States Patent No. 4,677,195, to which Chugai was a licensee.[41] EPO is a naturally occurring substance found in the human body essential to red blood cell production,[42] and the purified form was among a leading drug candidate to treat disorders such as anemia and renal anemia.[43] The '195 patent disclosed a method to isolate and purify EPO from urine.[44] Because of the large quantities of urine required, EPO did not offer commercial viability until Amgen succeeded in manufacturing EPO with recombinant techniques.[45] Again, to the dismay of many, the court held that Amgen's recombinantly produced EPO infringed Chugai's analog EPO.[46]

The disputes in *Scripps* and *Amgen* raised serious concerns about the power of patents to impede long-term progress in the biotech industry. Because of the *natural extracts doctrine*, a pioneer – by virtue of being first to isolate a compound from nature – can obtain a patent on not just the isolation process, but also on the isolated products as well. While this might incentivize current innovations, it also produces overly broad patents that can *block*[47] many important follow-on and related innovations.[48]

III) The broad reach of the natural extract doctrine

A) The subject matter restriction against the patenting of nature

To understand the significance of allowing purified compounds and genes to be patented, one should start with the traditional subject matter restriction again the patenting of nature. U.S. case law has long established that laws of nature, natural phenomena, abstract ideas, unapplied mathematical algorithms, and *product of nature* are not patentable subject matter.[49] A new mineral discovered in nature, a new plant found in the wild, rules of nature such as Einstein's celebrated equation $E=mc^2$ or Newton's law of gravity all do not constitute patentable subject matter.[50]

It might at first seem perplexing why discoveries of nature should not be patentable. Clearly discoveries of nature can be very important and useful (think for example, the discovery of electricity, the existence of microorganisms, and the laws of motion).[51] And since discoveries of nature often do require tremendous resources and risk undertaking, such discoveries would seem amenable to patent incentives. On the other hand, fundamental knowledge about nature occupies a special role in the advancement of knowledge. By opening doors to new fields of inquiries and applications, knowledge about nature serve as pillars on subsequent scientific and technological advancements can build.[52] While the privitization basic knowledge might spur basic research activities, the danger of such private monoplization pose to general progress has long been deemed high enough to outweigh the potential benefits to justify the preservation of the subject matter restriction against the patenting over nature.[53]

B) A constructive delineation of the artificial from the natural

Despite the long-standing subject matter restriction against the patenting of nature, U.S. law has long carved out a prominent though narrow exception for purified products isolated from nature in the biological and medical sciences. The law does so by constructively defining patentable "manufacture." Under the natural extracts doctrine, so long as a compound required human activity to obtain and conferred novel properties not found in the natural form, the compound would be considered patentable subject matter – even if the actual isolated product had always existed in nature. Pasteur was thus allowed, for example, to patent in 1873 his famous yeasts even no new species of yeasts were created as a result of the isolation.[54]

The modern origins of the natural extracts doctrine can be traced to Learned Hand's seminal *Parke-Davis* decision. In *Parke-Davis*, Learned Hand held that purified adrenaline was patentable subject matter because it required human effort to extract and the extracted product differed "not in degree, but in kind" from that of the naturally occurring form.[55] In *Parke-Davis*, Hand did not delve into the underlying science to ascertain whether a new compound was really created.[56] Instead Hand took a pragmatic, *layman's* approach[57] to delineate the boundary between artificial and natural.[58] Since purified adrenaline "for every practical purpose a new thing commercially and therapeutically," it constituted patentable subject matter.[59]

Modern courts have widely adopted Hand's approach. For example, in the *Amgen* and *Genentech*, the courts held the original patents over purified EPO and Factor VIII:C to be patentable subject matter because the products required human intervention to isolate and because the isolated products offered novel therapeutic properties for patients. In *In re Bergy*, the CCPA held a "biologically pure culture of the microorganism Streptomyces vellosus" to be patentable subject matter because such cultures "can be produced only under carefully controlled laboratory conditions" and allowed researchers to collect antibiotic lincomycin in sizable quantities for the first time.[60] In *Diamond v. Chakrabarty*, the Supreme Court held that a genetically engineered bacterium to be patentable subject matter because by offering the capability to break down multiple components of crude oil, the bacteria offered "markedly different characteristics from any found in nature" and constituted "a product of human ingenuity."[61]

C) The patentability of genes

Given the strong traditional subject matter restriction against the nature and the limited scope by which natural extracts doctrine have applied to purified compounds, one would at first guess that genes would not constitute patentable subject matter. After all, genes have existed for almost as long as life has existed on earth. They are the templates of life, passing from generation to generation, and containing instructions that direct all biological processes. If there were a product of nature, genes would seem it.

The law, however, has not treated genes by their functional roles in biology – as templates and directions for life, which presumptively would not be patentable.[62] Instead it has treated genetic materials – including DNA's, cDNA's, RNA's, EST's, SNP's, etc. – as chemical molecules – as a drug of sorts.[63] Like purified adrenaline, so long as genes require human effort to isolate and confer a special property (this usually means finding

some sort of utility for genes)[64] that the natural form does not require, genes can be patented.[65]

For many, the reduction of the genetic patentability debate into an issue of chemical patentability is disingenuous since the main purpose and effect of patenting genes is for control over the use of genetic information.[66] Genes are much more than the DNA in which they are encapsulated. Treating genes as chemicals, instead what they truly are as life directing instructions and templates, prevents the true merits of genetic patents from being examined.[67] Only by recognizing the broad ramifications gene patents have on research and innovations can the law fully confront the issues raised by such patents.[68]

IV) The Chakrabarty floodgate and patchwork of solutions

Prior to 1980, life forms and genes were considered a part of nature and thus not patentable subject matter. In the seminal Chakrabarty decision, the Supreme Court held that microorganisms were not categorically unpatentable since patentable subject matter "include anything under the sun that is made by man."[69] The decision has serious ramifications to all of biotechnology since it has opened a floodgate of patenting activities in biotechnology, not just over recombinant organisms, but also over genes. Today a large number of genes are being patented – from genes with known functions to those with little understood functions, from gene fragments (such as ESTs and SNPS) to complete genes. In an attempt to tame the floodgate, the P.T.O. and the courts have taken a couple of approaches. The PTO has required researchers to understand at least some functions of genes before taking out patents over the genes.[70] The Federal Circuit has tried to promulgate a new written specification requirement to invalidate many of the more "speculative" biotech patents,[71] creating an intra-Circuit controversy that the Federal Circuit Bar Association Patent and Trademark Appeals Committee has cited as one of the top conflicts in current Federal Circuit jurisprudence.[72]

A) The utility requirement as gateway to patentability of genes

The U.S. P.T.O. currently deems genes – more specifically "excised genes" – to be patentable subject matter as long as the patentee has characterized some of the gene's functions.[73] The emphasis on utility to control issuance of speculative, overly broad patents is, ironically, reminiscent of the Supreme Court's failed earlier attempts to rein in the speculative patents in general.[74] In *Brenner v. Manson*, the U.S. Supreme Court declared that the purpose of patents is to protect inventions with "substantial utility" – i.e. inventions with concrete present-day not speculative future uses.[75] The Court struck down a patent over a tumor-fighting drug candidate where the only indication of utility was that the compound's structure was similar to that of another compound that had previously been proven to inhibit tumor in mice.[76] Concerned that early, broad patents will impede subsequent innovations,[77] the Court famously pronounced, "a patent is not a hunting license";[78] a patent is "not a reward for the search, but compensation for its successful conclusion."[79] Subsequent case law would show that Brenner's specific utility approach would be too unwieldy to apply for controlling illicit patenting activities.[80] The line between early and applied research has been made even more difficult to draw since many biotechnological innovations claim as their primary

functions basic research tools.[81] "Substantial utility" has ceased to be a generally practiced doctrine,[82] except apparently in the context of genomics.

B) Federal Circuit's new quid pro quo written specifications requirement

35 U.S.C. § 112 requires patent applicant to submit "a written descriptions of the invention … in such full, clear, concise, and exact terms as to enable any person skilled in the art … to make and use the [invention], and shall set forth the best mode contemplated by the inventor of carrying out his invention."[83] § 112 is the statutorial basis of the so-called patentability disclosure requirement, which consists of three components – enablement, written specifications, and best mode. Enablement traditionally is considered to represent the *quid pro quo* of the *basic patent bargain*.[84] In return for a grant of monopoly rights, a patentee must disclose the invention in sufficient details to *enable* the public to practice it.[85] In a deal where society recognizes a temporary monopoly of the inventor's creation, the inventor must disclose enough to place the public "in possession"[86] of the invention.[87]

In trying to stem the flood of post-Chakrabarty biotech patents,[88] some in Federal Circuit believe it necessary to alter this time-tested *basic patent bargain* and elevate a separate requirement – the written specifications requirement – to be a *quid pro quo* requirement "separate and distinct" from that of enablement.[89] In *Regents of UC v. Eli Lilly and Co.* case, the court held that a patent claiming all DNA encoding vertebrate and mammalian insulin to be defective when it did not disclose the actual DNA sequences even though it did disclose an enabled method for obtaining those sequences.[90] In *Univ. of Rochester v. G.D. Searle Inc.*, the court invalidated a patent that disclosed a method allowing one skilled in the art to isolate a non-steroidal anti-inflammatory drug but not the actual structure of the drug by characterizing the invention as but "a research plan."[91] Responding to criticisms that the gist of disclosure has always centered on enablement (i.e. what an innovation contribute to the state of the art), not some ad-hoc judicially created standard, a panel of the Federal Circuit in *Enzo Biochem v. Gene-Probe Inc.* asserted that enablement served but one purpose of disclosure.[92] In *Eli Lilly & Co.*, a panel went declared that disclosure of all biological molecules categorically must include "a precise definition, such as by structure, formula, chemical name, or physical properties."[93] In *Union Oil Co. of California v. Atlantic Richfield Co.*, the court backpeddled a little when it held that "[t]he written descriptions requirement does not require the applicant 'to describe exactly the subject matter claimed, [but only that] the description must clearly allow persons of ordinary skill in the art to recognize that [the applicant] invented what is claimed.'"[94]

Articulating the court's apparent befuddlement, one judge recently explained, "[n]ew interpretations of old statutes in light of new fact situations occur all the time. I believe these issues have arisen in recent years [because] … the perceptions that patents are stronger [now] tempt patent owners to try to assert their patents beyond the original intentions of the inventors and their attorney. … Claims are now being asserted to cover what was not reasonably described in the patent."[95] Another judge explained, "'consider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been

described.'…This is surely part of the recent history of some biotechnology patents."[96] Judges fear that biotechnology patents are being used to carry out "fishing expeditions."[97] An exacerbated judge lamented, "among the problems in comprehension of the issues in a biotech context is that a functional description of DNA does not indicate which DNA has been invented. And simply acknowledging the presence of a DNA that serves a particular function, whose existence has been postulated since, perhaps, Mendel, plus a general process for finding it, is not a description of the DNA. It is a research plan at best, and does not show 'possession' of any invention."[98]

The attempt to create a new written specification requirement has drawn mixed reactions. Some have applauded the court's action as a necessary check on the explosion of biotech patents[99] while others have denounced it as an overly reactionary response that unnecessarily distorts established patent doctrines.[100] This author's view is more in line with the latter group. The traditional enablement doctrine has functioned as a gatekeeper of patentability for a wide variety of fields for a long time.[101] It is conceptually simple and rigorous. Before formulating an entire new doctrine on the basic quid pro quo of patenting, a formulation of what it is so unique about biotechnology that requires an additional doctrine beyond enablement must be articulated by its proponents.[102] Creating a new written descriptions requirement should not be casually undertaken. Such efforts could be dangerous as it risks unsettling established judicial expectations,[103] raises the specter of "judicial improvisation,"[104] and can lead to unintended harmful consequences.[105]

C) A better tack to controlling the Chakrabarty floodgate

Rather than relying on an unworkable notion of utility or inventing a new, unproven doctrine to control the floodgate of biotech patents, this paper will suggest that the better way to confront the biotech patent explosion directly is by taking a look at the root causes of the floodgate. Tracing the fundamental cause to the *natural extracts doctrine*, the rest of the paper discusses why this doctrine, and the broad patents it produces, is the main cause of today's problem in biotech patent proliferation and ought to be promptly abandoned if patents are to effectively incentivize long-term innovations in the field.

V) The natural extracts doctrine codifies outdated science and produces systematically overly broad patents

As alluded earlier, the natural extracts doctrine dictates that products extracted from nature constitute patentable subject matter as long as the extraction involves human intervention and the isolated product offers novel properties unavailable through the natural form.[106] This doctrine was doctrinally useful in bypassing the underlying science to allow for the patenting of natural extracts in despite of subject matter restrictions against the patenting of nature. This section discusses how the doctrine, created originally to shield judges from having to evaluate and justify patenting against the underlying technological realities, endangers the future of the biotech industry by enforcing a judicially presumed granularity at which innovations are evaluated, codifying old, outdated science, causing systematic confusion between process and product innovations and producing systematically overly broad patents.

A) The level of granularity at which innovations under the natural extracts doctrine are evaluated is unarticulated and judicially presumed

The boundary between the "natural" and "artificial" as defined by the natural extracts doctrine depends heavily on an unstated and uninformed level of granularity at which innovations are evaluated. Contrast the cases of *Funk Brothers Seed Co. v. Kalo Inoculant Co* and In re Bergy.[107] The *Funk Brothers* invention concerned a unique mixture of bacteria which when applied to certain leguminous plants enabled the plants to fix nitrogen directly from air.[108] The *In Re Bergy* invention concerned a purified culture of Streptomyces vellosus which allowed researchers to collect antibiotic lincomycin in sizable quantities. Under *Parke-Davis*, both microorganism cultures should be patentable subject matter: both inventions required human invention to produce and both products exhibited novel, useful properties. Yet, the courts held that the nitrogen fixing mixture in *Funk* was not patentable subject matter[109] while the purified lincomycin producing culture in *Bergy* was.

These two seemingly inconsistent results can be explained by the granularity at which the courts examined the invention. In *Funk*, the Court insisted on drilling down and evaluating the bacteria at a more microscopic level. The Court invalidated the patent on the ground that "[t]he combination of species produces no new bacteria, no change in the [disclosed] species of bacteria…. Each species has the same effect it always had. The bacteria perform in their natural way."[110] The Court concluded, "these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none."[111] On the toher hand, in *Bergy*, the court, in the true spirit of the natural extracts doctrine, assessed the invention at a high level of granularity from end user's perspective. Purified culture of Streptomyces vellosus became a new, artificial, patentable "manufacture" – as that is how an end user of these purified culture would view the product. Issues such as whether any new bacteria were created or whether each bacterium functioned individually the way as it had always in nature was not relevant when evaluated at this macroscopic level.

The discrepancies between *Funk* and *Bergy* illustrate the importance of the granularity at which innovations are evaluated under the natural extracts doctrine. Had the Court in *Funk* assessed the bacteria at a more macroscopic levels as in *Bergy* or *Parke-Davis*, the law should have deemed the *Funk* bacteria a patentable "manufacture." Had the *Funk* court treated the underlying innovation as a black box, all that would have mattered was that production of the bacteria required human efforts and the bacteria offered novel characteristics (i.e. nitrogen fixing) unavailable through the natural form. By the same token, had the *Bergy* court – or, for that matter, the *Parke-Davis*, *Amgen*, and *Scripps* courts – evaluated each of the respective final purified products at a low enough level of granularity, each court would have found no "artificial" product to have been created since in any of the cases, no new creation would have been created; all that would have occurred would have been a mere restructuring of natural elements.[112]

Even the invention in the seminal *Chakrabarty* case is not immune to the level of granularity at which it is evaluated. At the granularity of the organism level, the Court correctly pronounced that a new "manufacture" was produced: a new organism with a never before seen characteristic, the ability to break down oil slick, was indeed created.

However, at a lower level of granularity, say at the genetic level, the Court could easily have found no "manufacture." All that would have occurred was a reshuffling of genes (the transfer of an otherwise naturally occurring gene from one species to another) not unlike the reshuffling of bacteria in *Funk*.[113] At this level of granularity, the genes worked as they always did, and the newly endowed characteristic was a wholly predictable phenomenon resulting from the movement of the otherwise natural gene. Barring a modification to the actual genetic sequence, no "artificial" products would have been pronounced created.[114]

In summary, the natural extracts doctrine prescribes *as a matter of law* that the appropriate granularity at which innovations are to be evaluated to be high, without analysis whether this makes sense *as a matter of science or technology*. Unfortunately, at a high enough level of granularity all science and technology can appear magical.[115] As the following sections will discuss further, at too high a level of abstraction, isolated from scientific and technological grounding, the natural extracts doctrine inevitably creates gaps between the legal and technological understandings of innovations, produces overly broad patents, and hinders the ability of patents to promote long-term innovations.[116]

B) Evaluation of properties at end user, macroscopic level codifies outdated science

One of the problems with evaluating biotech innovations at too high a level of granularity is that it codifies outdated science. Historically, scientific fields usually move from higher to ever-lower levels of granularity as the field matures.[117] To incentivize innovations effectively, patents must accurately recognize at each particular time at what level of granularity the field is advancing and thus to incentivize appropriately the contributions made to the state of the start at the appropriate level of granularity.[118] For example, if creating recombinant organisms represent the state of the art of the biological field, then the creation of transgenic organisms by transferring genes between species (as in Chakrabarty) would constitute patentable subject matter.[119] However, if the state of the art has moved beyond, for example, where the main thrust of the state of art involves the actual creation of new genetic elements, then the "creation" of new organism by mere movement of otherwise natural genes would not constitute patentable subject matter.[120] Prescribing a judicially mandated granularity at which innovations by treating innovations like a black box and evaluating innovations by their impacts rather than their essence inevitably creates systematically overly broad patents.

One of the justifications often put forth in support of the natural extracts doctrine is the conceptualization of natural discoveries as manmade articulate. This can best be demonstrated by an appeal to a field like metallurgy. In metallurgy, novel mixtures are considered patentable "manufacture,"[121] even if its constituent components are well known and "natural." Supporters of the natural extracts doctrine would argue that if mere rearrangements of natural elements can give rise to patentable "manufacture" in metallugry, so should mere rearrangements of molecular elements such as bimolecular purification in biotechnology. The problem with such reasoning is that it ignores fundamental differences in the state of the art between the two radically different fields.

The thrust of metallurgy today, as it has been for centuries, is in discovering new combination of naturally occurring elements to produce heretofore-unavailable

properties. Thus, the mere rearrangement of natural elements can give rise to an innovation today as well as centuries ago as long as it produces novel properties.[122] On the other hand, modern biotechnology is a much different field. The thrust of biotechnological research today is about understanding and manipulating biological processes at the molecular and genetic level. It is already a very different field from that of traditional biology or chemistry. In the age of *Parke-Davis*, the alchemy of brewing up chemicals might dictate that the creation of any new substance that offered novel therapeutic effects constituted a concrete advance in the state of the art. Biotechnology today requires more. Innovations today must also be understood in terms of the molecular and genetic mechanisms involved.[123]

Consider a relatively simple technological example. Suppose I made an invention that doubled the speed at which web pages are displayed on computers by optimizing the memory component of a computer. At a high enough level of granularity, if one treated computers as black boxes, I would be credited in general with inventing a new computer that displayed web pages at twice the speed. That would be an over-recognization of my invention because any other innovation that would also double the computer web display speed would also be contributed to me. An expert would characterize my innovation in a more limited fashion by the contribution I made to the state of the art rather than the impact my innovation from the perspective of a lay person. In this case, I would only be credited with at most a memory innovation and an application of that memory invention to speed up computer browsing, but not a general computer browser speed enhancer innovation. For patents to recognize properly my inventive contribution, patents must evaluate my innovation at the proper level of granularity dictated by the state of the art.

It is important for patents to properly recognize innovations by contribution to the state of the art given the purpose of patents to incentivize innovations. If my patent credits me with doubling the browsing speed of computers in general, it would over-credit me for my innovation. Two problems can result. First it could over-incentivize such innovations, resulting in wasteful races or over-deployment of resources to the endeavor of doubling computer browsing speed. Second, it could also hamper subsequent innovative endeavors to double the speed of computer browsing as subsequent innovators would have to license from me to practice their inventions, even if they should achieve the doubling of browsing speed by completely unrelated techniques, such as by increasing the processor speed or increasing the Internet connection speed. It is thus critical to evaluate innovations at the granularity informed by the state of the art. If my patent correctly credits me with a memory innovation to double web browsing, endeavors to incentivize browser innovations would be properly incentivized, with subsequent innovations also appropriately freed and allowed to occur.[124]

Because the granularity at which technological innovations is evaluated should be informed by a good grasp of the state of the art, appealing to the perspective of a *person having ordinary skill in the arts* (PHOSITA)[125] to help delimit the boundary between the natural and artificial (and for that matter, on issues of non-obviousness and enablement also) is quite appropriate given the purpose of patents to incentivize innovations.[126] Because a person having ordinary skill in the arts is precisely the type of person a patent system would target to innovate, patent systems that align their comprehension of technological progress with such understandings will be most effective in promoting

innovative advancements.[127] While advances in some fields such as alchemy and metallurgy could be proximally understood by evaluating their societal impact, advances in most of today's science-based fields, such as biotechnology, must be evaluated by solid understanding of the underlying technological contributions, not just their effects.[128] When courts continue to specify as a matter of law that advances in science and technology by evaluated by their effects as under the natural extracts doctrine, the law risks codifying outdated science, missing the whole point of innovations altogether, and creating broad patents that in the long term disincentivize rather than incentivize innovations.

C) Evaluation of properties at end user, macroscopic level confuses product for process innovations

The natural extracts doctrine also greatly confuses the distinction between product and process innovations.[129] As a result of the confusion, the doctrine often allows the first to extract, by the mere fact of being first, to obtain a patent on the isolated product as well even though no innovation is made with respect to the product.[130] It is important to distinguish between product and process innovations because confusing product for process innovations result in overly broad patents and misaligns patent incentives with technological needs.[131]

Product patents confer rights over the isolated product to the first isolator. If patent understanding is to match that with the state of the art, a researcher should deserve a product patent only after he has created a new molecular structure. Because a product patent would preclude all future innovators of alternative, independent extraction techniques from obtaining a compound with the same molecular structure, product patents must be awarded carefully. Casually awarding overly broad product patents can greatly disincentivizes subsequent innovations, by disincentivizing subsequent innovations of alternative processes to extract the same products.[132] Process patents on the other hand confer rights of a process of isolating a product. It would only exclude future inventors from practicing the same extraction processes to extract a product but would free future innovators to invent alternative methods of isolating the same product. If all that an innovation involves is the extraction of an otherwise existing product from nature, and not the design or creation of a new molecule, process patents should provide more than enough incentives and protections. Process patents would properly incentivize such innovations by preventing others from using the actual process but would at the same time also protect future innovations by not reaching subsequent innovations involving alternative processes of extracting the same products.[133]

A problem with the natural extracts doctrine is that at too high a level of granularity, if innovations are to evaluated by their effects (e.g., therapeutic use) rather than their contribution to the state of the art, the distinction between product and process innovations become blurred. When adrenaline was purified, Hand did not look into whether the innovation involved just the extraction process or the actual creation of a new product. Instead, Hand merely looked to the impact on society (i.e. whether a new therapeutic use was created) and adjudicated, by legal construction, without regard to the underlying science, that a new product had been created. The problem is that at such a high enough a level of granularity, all process innovations could be made to look like

product innovations. But process and product innovations are distinct inventive steps. If patents are to incentivize technological progress, the law must look to the actual contribution made to the state of the art, not just to the effects of inventions. Unless the invention actually involves innovations in the isolated product (e.g., creation of a new molecular structure to stabilize an otherwise unstable purified product), patents should issue only on the purification process, not the product purified as well.[134]

VI) An Economics Framework for Evaluating Patents

The policy foundation underlying this country's intellectual property regime is decidedly utilitarian.[135] Article I, section 8 of the Constitution provides that Congress shall have the power to "promote the Progress of Science and useful Arts" by securing for limited times through establishment of intellectual property rights.[136] The Supreme Court has emphasized the utilitarian basis for patents by emphasizing, for example, that "[t]he patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather it was a reward, an inducement, to bring forth new knowledge. [Because t]he grant of an exclusive right … was … at odds with the inherent free nature of disclosed ideas…. [o]nly inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly."[137] Because of this utilitarian basis, one must view IP law more as a tool to effectively manage real world, economic activities[138] than the development or perpetration of legal doctrines despite a rich legal doctrinal history accompanying patents in this country.[139] This is especially true whenever an important new technology such as biotechnology arises. We must continually strive to be informed by the realities of landscapes new technologies and innovations create so we can create environments that promote, not hinder, new innovations. This is not easy, for this often requires policy and lawmakers to be conversant with both technology and law. Nevertheless, it is something that must be done. It would tragic – if not unconstitutional – if by misunderstanding new technologies and thus by force fitting old doctrines on new technologies, we should end up subverting technological progress in the process. This section presents an economics framework for evaluating patent law and policy that serve as a foundation for the next section to critique the current state of genomic patenting. It is hoped that these discussions will shed insights on not only the innovation process and associated economics, but also a more enlightened IP law and policy.

A) The "public goods" problem of innovations and the patent solution

The purpose of patents is to facilitate the development of useful innovations. Innovation needs a "helping hand" because it is a "public good":[140] innovations take resources to develop but are easily copyable, which inevitably by its nature without regulation confers benefits to others besides the inventor.[141] This externalization of benefits disincentivize the innovative enterprise because externalization can make it difficult for pioneers to even recoup the cost of their innovations.[142] Patents help to incentivize innovations by limiting the amount of externality through the grant of limited-term, monopoly rights to inventors over their inventions.[143] However, this must not go too far because patents are double edged swords which incentivize innovation on the one hand but can also impede innovation by impeding subsequent innovations and increasing the cost the public pays for innovations. In a properly balanced patent system, patents incentivize innovations not

so much by decreasing competitions as channeling and focusing the locus of competition for innovation.[144]

B) A more detailed analysis of both the immediate and follow-on costs and benefits of patents

Among the benefits often cited in favor of patents are that they: provide incentives to innovate; stimulate investment on patentable technologies; rationalize development of broad technology fields; enable disclosure and dissemination of technical knowledge;[145] provides a good yardstick for businesses to assess the value of technology startups.[146] Among the costs often cited are that they: encourage costly patent races that wastes duplicative, overlapping expenditures on R&D; create monopoly profits that result in deadweight loss to society; increase transaction costs by increasing the associated licensing and litigation activities; impede the development related and follow-on innovations through the creation of blocking patents.[147]

Cost-benefit analysis of the patent system is not new.[148] However, most of the literature has focused on the immediate tradeoff between the incentive of innovation and the underutilization of the innovation.[149] Influential works in this area include those by Nordhaus, Kaplow, Gilbert, Shapiro, and Klemperer.[150]

A framework such as one proposed by Merges & Nelson expands the scope of analysis by explicitly including both these immediate as well as the downstream costs and benefits of patents.[151] In this more comprehensive analysis, both the ability of patent's ability to incentivize innovations and cause underutilization of those innovation as well as ability of patents to internalize follow-on benefits and impede follow-on innovations are included in the cost-benefit accounting of patents.[152]

A brief example shows an expanded analysis works. Consider Morse's claim on telegraphy and his attempt to broadly claim also all methods of telecommunications, such as the radio and television.[153] The traditional justification for a telegraphy patent is that it serves to compensate Morse for devoting the resources and taking the risks to develop the telegraph. The cost of the patent will be born by society in the form of deadweigh loss and reduced overall utilization of the telegraph. A more expanded analysis will also attempt to answer how broadly a scope a patent should be awarded to an inventor given an invention. Should Morse's invention of the telegraph also entitle him to broad claim inventions to read on subsequent inventions such as telephones and radios that his invention will spur but others will still have to invent? The justification for allowing an inventor to broadly claim is that it can more fully compensate an inventor like Morse whose invention benefit society not only through the application of the telegraph, but also the spurring of many related inventions such as telephone and radio. Broad claims will thus more fully account for the benefits of an inventor's invention, but that benefit, as we will see, is counterbalanced by the tendency of broad patents to chill and disincentivize follow-on innovations as the patent will cover subsequent inventions that the broad claim will "read on" but that has not actually been "reduced to practice."[154]

In an ideal market where transaction cost can be ignored, the issuance of broad patents does not pose a problem.[155] There is no problem because even if patents read on follow-on innovations, the broad patents are not expected to block subsequent innovations

because subsequent innovators are expected to negotiate an agreement that share profits in a fair fashion. The parties are expected to be "fair" because it is in no one's interest to block truly worthwhile innovations. If the parties are rational and transaction costs are not too high, the inventors will work out a deal to allow subsequent innovations to develop.[156] Hence, according to established economic doctrines, the initial distribution of property rights (such as the issuance of overly broad patents) should not disturb the outcome of a Pareto superior solution (such as the commercialization of a valuable follow-on innovation), with the caveat that transaction costs can be ignored.[157] In fact, it is actually beneficial to award property rights generously (i.e. award broad patents) to ensure that all contributing stakeholders are brought into the negotiation so that each inventor can be properly awarded, when the time comes, according to the amount of contribution he makes, however small, at a time when the value of the innovation can be somewhat ascertained. Broad patents allow pioneers and follow-on innovators to contract at the latest opportune time to determine the actual, "optimal" distribution of property rights among them.[158]

Unfortunately, the problem with this model is that transaction costs cannot usually be ignored.[159] Determining mutually agreeable profit sharing is not always straightforward,[160] especially when the transaction costs caused by information asymmetry[161] and rent seeking is taken into account.[162] In reality thus, the determination of proper patent scope does actually matter. Patents must not be made arbitrarily broad because overly broad patents can and do impede subsequent innovations.[163]

C) The appropriate relationship between patent scope and the enabled innovation

This section discusses a framework for assessing appropriate patent scope.[164] Patent scope is described in this paper as either *broad* or *narrow* – with respect to the enabled technology as understood by a person skilled in the art (PHOSITA).[165] Given the goal of patents to enable innovations, a natural yardstick by which to compare scope is by referencing to the scope of enablement.[166] Broad patents are patents that cover subject matter that are broader than what is actually enabled by an invention. Conversely, narrow patents are patents are strictly limited to what is actually enabled by an invention. In other words, narrow patents are based strictly on what an inventor has enabled, not on what an innovation might inspire in the future.

i) Why patent scope should be wider than the enabled innovation

(a) Broad patents are needed to properly incentivize innovations

Perhaps the most compelling argument for broad patent's is Kitch's prospector theory of IP.[167] Kitch analogized patent claiming to mining.[168] Just as a miner who discovers a coalfield is entitled to all the coal in the vicinity, not just to the few granules he actually finds, an inventor is entitled to an area of technology *opened up by* the innovation, not just the invention he actually reduced to practice.[169] According to Kitch, to justify the risks and upfront resources needed to make an invention, inventors must be given "breathing room" to develop their innovations without fear that others, sitting on the sidelines conserving resources, learning from the pioneer's initiatives, will unfairly preempt them at later opportune moments.[170]

(b) Broad patents allow pioneers to coordinate follow-on innovations

Another justification for broad patents is Kitch's theory of coordinated developments.[171] Without broad patents, Kitch observed, intense competition would develop over a limited number of related and follow-on innovations, leading to tremendous waste of resources.[172] When a new area is opened up after a pioneering discovery, it would be more efficient to have one party manage and coordinate the subsequent developments.[173] Broad patents allow pioneering patentees – who are arguably best positioned given the interests, foresight, and expertise pioneers must exhibit in making pioneering innovations – to coordinate such developments.[174]

ii) Why patent scope should closely track the enabled innovation

(a) Narrow patents better align patent incentives with technological needs

Incentives work best when they align with the goals they are to foster. Since patents are to incentivize technological innovations, the patent landscape, which defines the incentives available to promote innovations, should match the technological landscape and the needs of the technological community.[175] A problem with broad patents is that they do not match the technological landscape. By over-recognizing what is invented, broad patents over-incentivise R&D activities[176] in the immediate timeframe – spurring risky ill-advised research[177] and unproductive R&D races[178] and siphoning off scarce resources from other socially valuable endeavors[179] – and under-incentivise in the later timescale – by prematurely removing legal rights to inventions that have not really been made.[180] The patent frenzy in biotechnology today may symptomatic of just such over-incentivization.[181] As patent rights are awarded faster than innovations are actually developed, as gaps develop between the legal and technological understanding of innovations, the effectiveness of patents to incentivize innovations decreases.[182]

Similarly, gaps between the storehouse of actual technological knowledge and patent library can also develop when the law awards narrow patents and under-recognizes innovations. Under-recognization occurs when the law recognizes less than what is actually invented. Over-incentivization inevitably follows under-recognization because when a previous innovation is under-recognized, the unrecognized parts of the innovations are attributed to subsequent innovators even though earlier innovators might have already made them.[183] Either over or under-recognization is counterproductive for the inventive process because either produces gaps, which undermine the effectiveness of patents to incentivize actual innovations.

Limiting patent scope to the scope of the underlying technological innovation is a much better way of incentivizing innovations because it strives to align the storehouse of actual technological knowledge and patent library. Defining patent scope by the enabled technology is also consistent with the *quid pro quo* of basic patent bargain, which requires that in the exchange of patent monopoly of invention disclosure, the inventor must give to the public the know-how to make use of the innovation in return for a patent monopoly.[184]

(b) Competition more effectively fosters innovations than central planning

Another advantage of limiting patent scope to the underlying innovation is that it is more consistent with the free market basis of the Western economy. Kitch argued against the use of competition for fostering follow-on innovations by emphasizing the downside of competitive waste. Nevertheless, these "disadvantages" of competition must be viewed against the benefits of competition.[185] Given the baseline norm of free market and open competition in Western (and increasingly the global) economies, competition rather than central command should be preferred as a model for creating innovations.[186]

Currently, there is no definitive proof whether the benefits of competition trumps those of of monoplies with respect to promoting innovations. But the dominant modern view seems to be that the benefits of a competitive innovation market outweigh the benefits of a monopolistic driven one.[187] This view makes sense especially given the uncertainty of innovations. If innovations are so uncertain, it is unrealistic to believe that entrusting the innovation process to a few major innovators (by granting them broad patents) will help to streamline innovations. Instead, it is probably better to keep patents narrowly tailored so that innovations can continue to bubble spontaneously from various diverse sources.

Another benefit of narrow patents is that it tends to spread competition throughout the innovation life cycle. This is beneficial given the observation that most technologies today develop in multiple stages through an extended innovation life cycle. Innovations come in chains. Rarely do inventions come as a one-shot deal. Spreading also helps to spur innovation by increasing the number of stakeholders involved throughout the innovation process, which, as discussed, take place in multiple stages.[188] Another benefit of narrow patents is that broad patents tend to concentrate incentives at one stage of innovation – usually at a very early stage in the innovative cycle as parties race to stake out major monopolies. By reducing the incentive to develop technologies during the most speculative stages of an innovation life cycle, narrow patents help to reduce such speculative wastes by spreading competition throughout the innovation lifecycle.[189]

(c) Broad patents over-incentivise R&D and merely shifts alleged competitive wastes over follow-on developments to early stages

One of the main benefits Kitch touted for broad patents is the reduction of competition. However, with closer analysis, it seems that broad patents may not so much reduce competitive waste[190] as shift the competitive wastes to earlier stages of the innovation process.[191] As discussed above, with narrow patents, competition is spread through out the innovation process. When patent scope is increased, raising the stake of an early legal win,[192] overall competition is not eliminated so much as overall competition become focused toward the earlier stages as inventors race to patent in anticipation of cornering a monopoly. Broad patents would thus most likely simply induce inventors to redeploy to earlier rounds resources they would have otherwise spent in later rounds, resulting in no net decrease in competitive waste.

(d) Coordination lacks empirical evidence

The evidence for coordination is also lacking. If coordination were important to pioneers, one would expect pioneers to target issue licenses to subsequent innovators. On the contrary, Merges & Nelson recently found that pioneers rarely grant targeted licenses;

instead the norm is to grant broad, general licenses.[193] Coordination also suffers conceptually given the uncertain trajectory of scientific innovations.[194] Given the difficulty in foreseeing the impacts of technological breakthroughs,[195] it would not seem to make sense to designate one party to *coordinate* follow-on innovations. In circumstances of true uncertainty, progress is best developed through vigorous competition among multiple well-qualified, well-incentivized parties (rather than the designation of a false sage) throughout the all phases of innovations.

iii) The relevance of technological field

The cost-benefit analysis has been discussed thus far independently of any insight into technological or market characteristics of industries.[196] Recent studies suggest however that the technological and economical context of the innovations should be taken into account in assessing the costs and benefits of patents.[197] Merges and Nelson abstracted three categories of innovation patterns under which patent scope should be evaluated and to which patent doctrines should be tailored. The three categories are fields with: 1.) independent spheres of inventions; 2.) mutually dependent, cumulative spheres of inventions; and 3.) science-based (breakthrough) inventions that opens up many follow-on innovations.[198]

(a) Field with independent spheres of inventions

Fields with independent spheres of innovation, or "discrete innovations," involve industries where innovations take place relatively independently of each other. In such industries, the original pioneer either develops all the related technologies together or is expected to undertake most of the follow-on and related developments of the innovation.[199] Examples include the traditional pharmaceutical and chemicals industries.[200] Once a drug is developed, for example, the innovation is complete and stands on its own. There are usually little follow-on innovations, but even if there are, the original pioneers undertake most of those developments.[201] In such environments, the cost of overly broad patents – the chance for patents to disincentivize others from innovating – is low, and broad patents can usually be awarded without too much harm.[202]

(b) Fields with mutually dependent, cumulative spheres of inventions

Fields with mutually dependent, cumulative spheres of inventions involve industries where technology develops cumulatively and incrementally, often with lots of mutual dependence. The communications and semi-conductors industry represent prototypical industries. A state-of-the-art microprocessor, for example, can feature a ground breaking proprietary technology but yet, without depending also on a wide diversity of prior, cumulative innovations, the chip would not be able to function.[203] In such an environment, any incentive to holdout and rent seek[204] against other inventors is muted. When innovators fall on both sides of the rent seeking fight, they quickly learn to be more amenable in sharing their technologies,[205] lowering transaction costs related to IP for the entire industry.[206] As an observer recently noted, in cumulative industries, "patents are usually legal bargaining chips [for cross-licensing] rather than the traditional prize for winning a technology tournament [to blocking out a market]."[207] The cost of overly broad patents in cumulative, incremental industries is thus, like that of independent spheres industries, manageable.[208]

(c) Fields with science-based (breakthrough-based) inventions

Fields with science-based inventions involve industries where scientific or technological breakthroughs open up large areas of new opportunities for subsequent developments.[209] Recent examples include the biotechnological and superconductivity industries.[210] The cost of overly broad patents is very high in science-based industries.[211] Unlike industries with independent spheres of innovations, many competitors usually participate in the effort to develop follow-on technologies.[212] The potential for broad patents to block subsequent innovations is high because many subsequent innovations will be expected to build upon prior breakthroughs.[213] However, unlike the case in cumulative, mutually independent industries, because the IP dependencies among stakeholders in science-based industries are asymmetric,[214] the incentive to ameliorate the problem of transaction cost is not high.[215] It is thus very important to try to get the scope of patent right in science-based industries.[216]

iv) Historical lessons on proper patent scope

Scholars have debated the question of appropriate patent scope for centuries.[217] Even basic questions such as to what extent the patent system is actually incentivizing innovations remain unsettled.[218] After studying a few seminal cases of broad patents and their effects on subsequent technological progress, Merges and Nelson recently offered some qualitative insights regarding proper patent scope.[219] A key observation is that in industries where the development of follow-on technologies is resource intensive or technologically uncertain, patent scope over the pioneering technology should be narrowly tailored to ensure that patent incentives and competition are preserved for subsequent phases of innovations.[220] Merges and Nelson have also noticed that history offers many examples where broad patents have led to impediments of follow-on developments but few if any example where broad patents have facilitated the development of follow-on innovations.[221]

VII) An incentive-based case against applying the natural extracts doctrine in biotechnology

As has just been discussed, the purpose of intellectual property protection is to "promote the Progress of Science and useful Arts." And as has just been argued, in order for legal incentives to effectively incentivize technological progress, the legal incentives must be congruent with technological needs. What the patent system recognizes as invented must have been recognized as such by the technological community; and conversely, what the technological community recognize as still needing work must be recognized by the patent system as still needing work and not be prematurely recognized.

The problem with the natural extracts doctrine is by setting the level at which innovations are evaluated at too high a level of granularity, it produces overly broad patents that distorts patent incentives. As the patent archive grow disproportionately with real technological progress, the effectiveness of patent incentives to incentivize innovation inevitably weakens.[222] In the section above, "The natural extracts doctrine codifies outdated science and produces systematically overly broad patents," I theorized that this unfortunate result arose from the courts' misinformed application of old patent doctrines to new technological landscapes. By evaluating technologies at too high a level of

granularity and force fitting of legal doctrines to new technologies without sufficient appreciation of the new technological landscapes, courts have sometimes eveolved patent law to a stage where it potentially risks impeding future innovation. The following section briefly discusses some of the key themes discussed above to the context of the biotech industry.

A) If patents are to incentivize scientific and technological innovations, patent incentives must align with technological needs

i) Incentivizing technological innovations at every stage of innovations

If patents are to incentivize technological innovations, patent incentives must align with technological needs.[223] Any gap that develops between legal and technological understandings would decrease the effectiveness of patents to incentivize technological progress.[224] This is especially true in industries that depend on multi-round innovations such as biotech. A cure for a disease like cancer, for example, will require breakthroughs through several rounds of innovations.[225] A break in any link of the chain of innovations will greatly affect the overall progress of the entire field.[226] If patents are to incentivize overall progress and not break the chain of innovations, patents must be narrowly tailored so patent incentives can be preserved to incentivize innovations every each successive round.[227] Broad patents should be avoided because they tend to focus over-narrowly on certain rounds (i.e., usually the earlier rounds) at the expense of subsequent rounds.

ii) Reducing the high cost of blocking patents in a multi-round innovations

Besides prematurely removing incentives from subsequent rounds of innovations, broad patents can also directly impede subsequent innovations by creating blocking patents.[228] The *Scripps* and *Amgen* cases showcased how serious a threat this can be. While blocking patents in a world without transaction costs may actually serve to incentivize innovations by enabling inventors to more fully internalize the benefits of their creations, in reality, transaction costs cannot be ignored in reality. As the *Scripps* and *Amgen* cases showed, the cost of blocking patents to impede innovation is great. Worse still, as bad as the *Scripps* and *Amgen* cases seemed, the adverse consequences of overly broad patents in the genetic context will be orders of magnitude worse. *Scripps* and *Amgen* involve purified compounds – subjects that are traditionally associated with independent spheres of innovation.[229] Genetic patents will touch upon subject matter in a much broader area of biology.[230] Genes are the basic building code of life. Should patents genes ever block, entire fields of research in medicine, pharmaceuticals, and basic biology will suffer.

While the effects of blocking patents can be somewhat alleviated in some industries featuring mutual dependence of innovations,[231] this is unlikely to happen in the case of genes given the asymmetric dependence of biotechnological innovations.[232] Because the role of research and applications are more delineated among participants in biotech, the motivation to create pools and cross licenses that lessen the adverse effects of patent blocking will be correspondingly lower. Given the dramatically super high costs of blocking patents in biotech, it is especially critical to take steps that decrease the cost of blocking patents in multi-round industries such as biotech. An important place to start is to scrutinize the scope of biotech patents to ensure they are not unnecessarily broad.

iii) Re-emphasizing the traditional scientific over the modern patent based incentives

Broad patents are sometimes justified on the ground that patent incentives are needed to compensate for extra-technological factors such as market, regulatory, and enforcement risks.[233] Pharmaceutical product patents, now required throughout the world as part of the WTO TRIPs agreement,[234] are justified on the ground of the tremendous resources need to be expended to test and validate a drug target. Such patents exist to deal with not just technological but also market risks. It is emphasized that even after making the scientific and technological innovations involved in identifying a drug candidate,[235] pharmaceutical companies must be further incentivized, with a broad product patent, to expend resources to push the drug through the FDA and to develop the market. While patents have been broadened to compensate for such extra-technological factors in pharmaceutical industries,[236] *such practices should be limited rather than expended*.

In particular, patents must not be so used in the broader science-based biotech industries – for at least two reasons. First, since the development of science is of core importance, patents should focus on incentivizing scientific and technological innovations, not overcoming regulatory or market hurdles. Patent is already blunt enough of an instrument to regulate just incentives of innovation, its use to regulate also incentives of marketplace adversely strains the system. The risk of such practices to distort innovation incentives is too great. If industries need help to overcome extra-technological hurdles, separate frameworks outside of patents should be employed. Perhaps tax subsidies can be offered.

Second, as seen above, while too much patent incentives can impede technological progress by incentivizing patent races and blocking patents, it is not clear whether too little patent incentives will cause equally as much harm. Some have argued that in science-based industries, patents need not be made the pillar of an industrial policy to promote progress. The existence of non-patent incentives[237] such as traditional science-based incentives[238] may already go a long way toward incentivizing much of scientific and technological innovations in biotech. Indeed, some recent studies have shown that many research-intensive industries do not rely as heavily on intellectual property protection to incentivize R&D as commonly believed.[239] Given the fact that the cost of broad patents is high (i.e. broad patents can block subsequent innovations)[240] and narrow patents low (i.e. extra-patent, science-based incentives exist to make up for potential incentive deficiencies) in science-based industries, it should be wise policy to err on the narrow patents where data is not justify the strength patents. In biotech, it would probably be wise to select the overly narrow patents instead of the overly broad ones produced in science-based industries.

B) Because technological directions are difficult to predict, competition should be preferred over central coordination

As discussed above, the economy of this country is based on a competitive rather than a central command system.[241] It should thus not be hard to argue that given that base line, innovations should be fostered by competition rather than central command where possible.[242] In truly uncertain environments, where technological trajectories are truly difficult to predict, patent incentives should thus be made minimum. It does not make

sense to designate a party to manage follow-on innovation activities when no one party, including the original pioneer, is in any better position to foresee the future trajectories of a new technology.[243] Where the expertise needed to make related innovations is broad[244] and the risks and investments involved in each round of innovations[245] is great, and where innovation bubbles more by happenstance than through heavy investment, narrow or even overly narrow patents should be preferred to preserve competition for latter stages of innovation.

In biotech, where it is not possible to predict which round of innovations will be most important (if there is such a round), it is paramount to distribute competition through all phases of innovations rather than too early in the cycle of innovation.[246] Since narrow patents tend to distribute competition throughout the innovation life cycle while broad patents tend to concentrate competition early in the innovation life cycle,[247] a doctrine such as the natural extracts doctrine that prescribes categorically broad patents must be abandoned.

C) Incentives of original pioneers

One of the alleged benefits of broad patents is that, by allowing pioneers to internalize some of the benefits of follow-on innovations, broad patents more completely incentivize pioneers for their original innovation.[248] Further examining will show that this is a dubious proposition in science-based industries where follow-on developments are so unpredictable. While pioneers may indeed factor internalization of potential follow-on benefits into their original incentives to innovate, pioneers probably would not do so in unpredictable, science-based industries given how difficult[249] technological trajectories are to predict.[250] Many innovations start out innocuous only to make a large impact later; many hyped innovations turn out not to make much impact at all.[251] In such circumstances, pioneers more likely will base their decision to innovate on the benefits they expect to derive from their immediate invention rather than any potential follow-on benefits. Hence it is not necessary to risk broadening patent scope to try to better incentivize inventors when inventors do not take into account such incentives in making innovations.

VIII) Conclusion

This paper has highlighted the utilitarian basis on which patent law is founded and suggested that a policy aimed at promoting progress rather than perhaps preserving property doctrines ought to be the basis of patent law. As science and technology play ever-increasing roles in societal welfare, a well designed patent policy has a potential to play important roles in increasing our well being by incentiving long-term technological progress. To incentivize such progress, the law must pay more attention to realities demanded by new landscapes rather simply perpetuating old doctrinal principles. Reforms must be advanced that narrow patents are promulgated to ensure that patent incentives better align better with technological realities than allowed under today's broad patent system.

The natural extracts doctrine has played a defining role in opening the biotechnology patent floodgate by broadly delineating the scope of "artificial manufacture." Unfortunately, it has done so by de-emphasizing the contribution an innovation makes to

the state of the art and emphasizing the effect an innovation bestows to society. By creating a legal, constructive delineation of what is natural and artificial, it has effectively eviscerated the subject matter restrictions against nature and has been greatly responsible for the current floodtide and crisis of patents in biotech.[252] Given the importance of technological innovation in biotechnology and the stakes involved in having a healthy biotechnological industry, it is important that patent reform in this sector be carried out as soon as possible. Because biotechnology innovations take place in multiple, successive steps, patent scope must be made to match the underlying innovations. Categorically broad patents that ignore the underlying technological contributions to the state of the art and mistaken, for example, process for product innovations must be eliminated. Overly broad patents incentivize today's innovations at the expense future innovations.

There are alternative, more effective ways to incentivize biotech innovations without sacrificing future innovations. In the pharmaceutical context, for example, where the innovations typically involve a combination of process and use innovations,[253] the inventions should be adequately incentivized by a combination of process and use patents. Similarly, in the biotech genomic context, where the advances typically involve discoveries over the use and application (and not creation) of genes for diagnostic and therapeutic purposes[254] – and not the *sequencing*[255] or *basic discovery*[256] of genes – genomic innovations should be incentivized[257] by use rather than product patents.[258]

To reverse the damage and legal confusion that decades of application of natural extracts doctrine have produced, the subject matter restriction must be resuscitated through a more informed understanding of the underlying technological innovations involved. A subject matter delimitation of what is nature and what is not, as understood under a PHOSITA standard similar to that used for obviousness and enablement, is a good first step. If the incentivization of innovational progress is important, the natural extracts doctrine, together with the overly broad patents the doctrine has promulgated, must be promptly abandoned.

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[1] See generally, e.g., Roberto Mazzoleni & Richard R. Nelson, "The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate," 27 Research Policy 273 (1998).

[2] This system has been largely expanded to the international arena, most ostensibly through WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), originally negotiated in the 1986-94 Uruguay Round. See http://www.wto.org/english/tratop_e/trips_e/trips_e.htm.

[3] *See, e.g.,* Fed'l Trade Comm'n, infra note 186, at 867 (the Federal Trade Commision recently noting that despite the ability to incentivize innovations, overly broad patents also "deter market entry and follow-on innovation by competitors and increase the potential for the holder of a questionable patent to suppress competition.").

[4] *See, e.g.,* Suzanne Scotchmer, "Innovation and Incentives," 138 (MIT Press, Cambridge, Massachusetts, 2005)

[5] See discussions surrounding infra notes 35-46.

[6] In 2004, U.S. biotech companies marketed approximately 230 drugs, including 13 therapeutic antibodies; filed fifty-five FDA New Drug Applications (NDA), treating a wide variety of conditions including cancer, congestive heart failure, pain and diabetes; and raised $16.9 billion in capital in the U.S. alone. "Product Success and Strong Financials Drive Biotech Industry's Maturation According to Ernst & Young's 2005 Global Biotechnology Report," (2005), available at http://www.ey.com/global/content.nsf/US/Media_-_Release_-_06-01-05DC. Expectations are so high that many pundits have proclaimed the twenty first century to be a "biotech century." *See, e.g.,* Kenneth I. Shine, *Welcome*, in NATIONAL RESEARCH COUNCIL, U.S. DEP'T OF ENERGY, SERVING SCIENCE AND SOCIETY IN THE NEW MILLENNIUM 1, 1 (1998) (proclaiming that, whereas "the 20th century will be known as the century of physics and astronomy," "the 21st century

will be the century of the life sciences in all their ramifications"). *See, also,* JEREMY RIFKIN, THE BIOTECH CENTURY: HARNESSING THE GENE AND REMAKING THE WORLD (New York, 1998). For an overview of recent biotech advances, see, e.g., 291 Science 1304 - Venter - the Human Genome.pdf.

[7] Cohen e. al., "Construction of Biologically Functional Bacterial Plasmids In Vitro," 70 Proc. Nat. Acad. Sci. 3240 (1973).

[8] There are about 1500 biotech companies in the U.S. in 2002. The American biotech industry has a market capitalization of about $US 225 billion in 2002 on revenues of $33 billion. Biotechnology Industry Organization Editors' and Reporters' Guide to Biotechnology 2002-2003. p. 2-3, Washington DC: Biotechnology Industry Organization; Michael Rosen, "The mushrooming of biotechnology in the U.S.," (Wisconsin Technology Network 2006), at http://wistechnology.com/article.php?id=2768.

[9] See, "Patenting in the biopharmaceutical industry - comparing the US with Europe," Drug Plus International
(August 2002 Volume 1 No 1), available at http://scientific.thomson.com/free/ipmatters/pii/8180019/ (describing patents as "the lynchpins of the biopharmaceutical industry."); Lila Feisee, speech titled "Anything Under the Sun Made by Man," at http://www.bio.org/speeches/speeches/041101.asp (2001) (the Director for Federal Government Relations and Intellectual Property of the Biotechnology Industry Organization proclaiming that "without patents, there would be no biotech industry and no innovative drug development"); Brian A. Jackson, Innovation and Intellectual Property: The Case of Genomic Patenting, 22 J Policy Anal Manage 5, 13 (2003); Michael J. Malinowski, "The secret to US success in biotechnology," (Biotechnology and globalization viewpoint, 1999) at http://www.cid.harvard.edu/cidbiotech/comments/comments14.htm (pointing out that "[b]iotechnology's extraordinary evolution in the US is largely attributable to supportive federal policy … which provides incentives for academic-industry research alliances (AIRS) … [and] intellectual property policy, beginning with recognition of the potential patentability of inventions involving living matter in the early 1980s."); Frederic M. Scherer, *The Economics of Human Gene Patents*, 77 Acad. Med. 1348, 1351 (2002) (citing Carnegie-Mellon survey which placed R&D mangers of medical equipment and drugs related product organizations from among 34 industry groups as the most enthusiastic about patents as mechanisms for appropriating intellectual property value); Reid G. Adler, Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization, 257 Science 908, 908 (1992).

[10] As an example, consider the Bayh-Dole Act (Patent and Trademark Amendments Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended in scattered sections of 35 U.S.C.), which allow research grantees to take out patents on innovations derived from public funded research. For example, Yale would not have been able to commercialize its aids treatment drug d4T without possessing the patents needed to attract partnership with the private sector, in this case Wyeth-Ayerst Pharmaceuticals. Publicly funded innovations developed in U.S. Universities are now routinely patented to attract interests from the private industry to commercialize University created innovations. Andrew Dervan, "Can Yale help end the AIDS plague?" October 18, 2001, Yale Daily News, available at http://www.yaledailynews.com/article.asp?AID=16677. Not everyone is so sanguine about the Bayh-Dole Act though. See, e.g., William M. Landes & Riachard A. Posner, The Economic Structure of Intellectual Property Law (Harvard University Press, 2003), 316 (noting how because Bayh-Dole have "induced universities to substitute away from basic research … the result may have been a net social loss."); David C. Mowery et al., "The Effects of the Bayh-Dole Act on U.S. University Research and Technology Transfer," in *Industrializing Knowledge: University-Industry Linkages in Japan and the United States* 269, 274 (Lewis M. Branscomb et al. eds., Cambridge, Mass: MIT Press 1999) (suggesting that the economic theory behind the Bayh-Dole Act is "based on little evidence"); Darren E. Zinner, *Medical R&D At The Turn Of The Millennium*, 20 HEALTH AFFAIRS 202, 205 exhibit 4, *available at* http://content.healthaffairs.org/cgi/reprint/20/5/202.pdf (noting that despite the greater share of R&D undertaken taken by the private industry, up to two-thirds of drug R&D is still done by academia and federal agencies); Public Citizen Congress Watch, *Rx R&D Myths: The Case Against The Drug Industry's R&D "Scare Card"*, 8-10 (Washington, D.C., July 2001), *available at* http://www.citizen.org/documents/ACFDC.PDF (arguing that despite massive private expenditures, most of the drug breakthroughs still come from academia and federal agencies rather than private industry).

[11] Anomymous, "Gene patents and the public good," 423 Nature 207 (2003) (observing that there is a "growing concern among biomedical researchers that broad patents on genetic sequences may, in some cases, have a stifling effect on research and negative consequences for public health" and that "something

seems to be out of balance," and also urging studies and reforms "to ensure that the patent system continues to do its job of stimulating innovation for the public good"); "Integrating Intellectual Property Rights and Development Policy," 126 (Commission on Intellectual Property Rights, London, 2002), available at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf (questioning whether broad patents in biotech are "stimulating genuine invention[s]" and not "protecting minor and intermediate technologies…."); Scott A. Chambers, Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences, 23 AIPLA Q.J. 53 (1995); Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter As To The Patentability Of Certain Inventions Associated With The Identification Of Partial cDNA Sequences*, 23 AIPLA Q.J. 1 (1995); Andrew T. Kight, Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines in Light of Brenner, 73 Ind. L.J. 997, 1015 (1998); Nathan Machin, Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act, 87 Calif. L. Rev. 421, 455 (1999) (doubting whether ESTs would satisfy the utility requirement).

[12] *See, e.g.,* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698, 698 (1998) (warning that "[a] proliferation of intellectual property rights upstream may be stifling life-saving innovation downstream."); Jackson, supra note 9, at 10-11 (noting that "[t]he same gene could be relevant as a drug target, a pharmaceutical itself, part of a diagnostic test, a subject of bioengineering, a gene therapy target, and other applications. Knowledge of gene sequences and their functions can be as powerful and far reaching as any basic piece of scientific knowledge that might serve as the basis for many later discoveries and innovations."); Fed'l Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, Executive Summary 7-8 (2003) (Recommendation 1), available at http:// www.ftc.gov/os/2003/10/innovationrpt.pdf, reprinted in 19 Berkeley Tech. L.J. 861, 866 (2004) ("[M]any participants in and observers of the patent system expressed significant concerns that, in some ways, the patent system is out of balance with competition policy. Poor patent quality and legal standards and procedures that inadvertently may have anticompetitive effects can cause unwarranted market power and can unjustifiably increase costs."); Adam B. Jaffe, "The U.S. Patent System in Transition: Policy Innovation and the Innovation Process," 29 *Research Policy* 531, 555 (2000). (concluding that there is "widespread unease that the costs of stronger patent protection may exceed the benefits. Both theoretical and, to a lesser extent, empirical research suggest this possibility.");Jackson, note 9, at 23; Landes & Posner, supra note 10, at 316; Janice M. Mueller, "No Dilletante Affair': Rethinking the Experimental Use Exception to Patent Infringemnet for Biomedical Research Tools," *76 Wahsington Law Review 1* (2001).

[13] *See* Scherer, *supra* note 9, at 1349; In the gene context … Jackson, supra note 9, at 6 (Because genes "also encode information—a portion of the programming that makes life possible—they have a range of potential uses that continues to expand as we learn more and more about biotechnology. This "hybrid" nature—that a gene sequence is both technology and information—can make it difficult to judge the scope of a sequence patent and, as a result, make its effect on innovation difficult to predict.").

[14] Jackson, *supra* note 9, at 15 (questioning whether "the simple act of disclosing a sequence is of sufficient value to merit the societal reward of monopoly rights"). The biotech revolution is just beginning. There is still so much more to learn. Surprises continue to pop up along the way. For example, despite the entrenchment and power of the traditional one-gene-one-protein translation model, researchers are just recently beginning to understand how the addition of extra copies of genes can suppress rather than amplify the expression of the gene. *See* Guru T., *A silence that speaks volumes*, 404 NATURE 804 (2000). Scientists are also just beginning to understand how genes, aided surprisingly by viral retrotransposons, could code through variable gene splicing for multiple proteins! *See* Gil Ast, *The Alternative Genome*, 292 Scientific American 58 (2005). *See also*, Jackson, *supra* note 9, at 18 (noting for example that "even the seemingly simple process of copying a gene from the genome and translating it into protein is a very complex process. The sensitive regulatory systems that modulate the amount of proteins that are produced and how they are modified may involve tens or even hundreds of other biological molecules. Once a protein is made, its actual functioning in the body is even more complex, involving" complex networks of molecular and signaling pathways.

[15] For example, the functional and regulatory role of the genes still need to be characterized; the underlying biochemical pathways still need to be studied; and diagnostic and therapeutic techniques still need to be invented. One of the most poster cases on the power of patents to block innovation related to the experience of a research team to study the effect of genetically modified vitamin fortified rice to reduce the

incidence of blindness arising from vitamin A deficiency. Researchers had to negotiate licenses involving seventy patents with over thirty-one institutions just to license the rice! David E. Adelman, "A Fallacy of the Commons in Biotech Patent Policy," 20 Berkeley Tech. L.J. 985, 997 (2005).

[16] See, e.g., Scherer, note 9, at 1364 (proposing research exception as a mechanism to control the negative impacts of genetic patents).

[17] Scherer, *supra* note 9, at 1348.

[18] *See, e.g.,* Richard F. Harris, *Patenting genes: is it necessary and is it evil?*, 10 Curr. Biol. R174, R174 (2000).

[19] See, e.g., OECD Science, Technology and Industry Scoreboard 2003, available at http://www1.oecd.org/publications/e-book/92-2003-04-1-7294/execsumm.htm (presuming that patenting is a measure of innovation)

[20] See, e.g., Harris, note 18, at R175 (Describing how "intellectual property can now be manufactured by the bushel barrel. Mostly what it requires is some DNA sequencers, a cadre of PhDs and a computer algorithm that can spot homologies between novel stretches of DNA and sequences of known function. Presto, a gene patent is born…."). James Watson, one of the discoverers of the helical nature structure of DNA, has characterized today's mass-structural sequencing effort as work too routine ("monkey work") to merit patent protection. *Who owns your genes?*, The Economist, July 01, 2000 (U.S. Edition).

[21] See discussion surrounding infra notes 62-67.

[22] ESTs stands for Expressed Sequence Tags. According to the Genbank science primer, "ESTs are small pieces of DNA sequence (usually 200 to 500 nucleotides long) that are generated by sequencing either one or both ends of an expressed gene. The idea is to sequence bits of DNA that represent genes expressed in certain cells, tissues, or organs from different organisms and use these 'tags' to fish a gene out of a portion of chromosomal DNA by matching base pairs." "ESTs provide researchers with a quick and inexpensive route for discovering new genes, for obtaining data on gene expression and regulation, and for constructing genome maps. Today, researchers using ESTs to study the human genome find themselves riding the crest of a wave of scientific discovery the likes of which has never been seen before." "ESTs: GENE DISCOVERY MADE EASIER," at http://www.ncbi.nih.gov/About/primer/est.html.

[23] See 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 AIPLA Q.J. 1, 3, 13-14, 16-17 (1995).

[24] See, e.g., 23 AIPLA Q.J. 1, 13-14 & 38.

[25] Jackson, note 9, at 8.

[26] Doubts about appropriateness of genetic patenting are also raised by the significant increase of defensive patenting in genomics. People are patenting not to protect or disclose inventions, but to build up bargaining chips that can be used to alleviate the sting of or block potential lawsuits. See, Adelman, supra note 15, at 997 (noting that there has been "a significant rise in defensive patenting, particularly in the genomic sciences"); "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy: Executive Summary," 19 Berkeley Tech. L.J. 861, 868 (noting that many companies are forced to play patent game and create "defensive patents" that "have no ... innovative value in and of themselves" to avoid being sued even though resources "could have been better spent on developing new technologies."); Joshua D. Sarnoff, "Abolishing the Doctrine of Equivalents and Claiming the Future After Festo," 19 Berkeley Tech. L.J. 1157, 1203 (observing that "the patent system operates only as a tax on innovation" as many business now patent not to disclose innovations, but to play the patent game to prevent litigation claims).

[27] See Jackson, note 9, at 15-16 ("[S]ince research groups are willing to perform these tasks and disclose their results without the reward of patent rights, society should pay no premium to other firms or individuals to do so."). See also, Bruce Alberts et. al., "Molecular Biology of the Cell," 500-09, (Garland Science, 2002, 4th Edition); Adler, supra note 10, at 908 (discussing how the sequencing process has become increasingly routine and automated).

[28] E.g., Scotchmer, supra note 4, at 242.

[29] Rebecca S. Eisenberg, Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences, 49 Emory L.J. 783, 784 (2000).

[30] SNPs are Single Nucleotide Polymorphisms. SNPs constitute "a small genetic change, or variation, that can occur within a person's DNA sequence. … By studying stretches of DNA that have been found to harbor a SNP associated with a disease trait, researchers may begin to reveal relevant genes associated with a disease." "SNPs: VARIATIONS ON A THEME," at http://www.ncbi.nih.gov/About/primer/snps.html.

[31] Harris, note 18, at R175.
[32] 77 Rebecca S. Eisenberg, Why the Gene Patenting Controversy Persists, 77 Acad Med 1381, 1381 (2002).
[33] Id. at 1381; Rebecca Dresser, Ethical and Legal Issues in Patenting New Animal Life, 28 Jurimetrics J. 399, 434-35 (1988).
[34] See, e.g., Statement of Robert Barr, IPR department of CISCO, to 2002 FTC Hearings on Anti-Competitive Effects of Patents, 3-4, available at http://swpat.ffii.org/papers/ftc02/cisco/ftc020228-cisco.en.pdf ("So obtaining patents has become for many people and companies an end in itself, not to protect an investment in research and development, but to generate revenue through licensing ("holding up") other companies that actually make and sell products…. They try to patent things that other people or companies will unintentionally infringe and then they wait for those companies to successfully bring products to the marketplace. They place mines in the minefield. [They] … play the patent system like a lottery…. They benefit from the high cost of litigation … hoping that people will pay even if they don't infringe…. [C]onsulting firms [form] … to help people 'mine' their patent portfolios for patents that even they didn't know they had. It's hard to see how this contributes to the progress of science and the useful arts.")
[35] *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 666 F. Supp. 1379, 1393 (N.D. Cal. 1987).
[36] *See, e.g.*, Michael S. Greenfield, NOTE: RECOMBINANT DNA TECHNOLOGY: A SCIENCE STRUGGLING WITH THE PATENT LAW, 44 Stan. L. Rev. 1051, 1052 n.8.
[37] *Scripps I*, at 1383.
[38] *Id*. at 1384.
[39] *Id*. at 1394. On the case history, see *Scripps Clinic & Research Found. v. Genentech, Inc.*, 707 F. Supp. 1547, 1550-52 (N.D. Cal. 1989) [hereinafter Scripps II] (court setting aside infringement rulings on the ground that the '011 patent was invalid for failing to disclose "best mode" and on grounds of inequitable conducts) and *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1571-74 (Fed. Cir. 1991) [hereinafter Scripps III] (court reversing invalidity rulings and remanding for further proceedings). The parties eventually settled, apprently in terms favorable to Genentech. *See Genentech Litigation Settled*, MARKETLETTER, January 24, 1994, LEXIS, Nexis Library, News Group File; *Genetech Wins Extra Royalties in Clotting Product Settlement*, BLOOMBERG NEWS, January 19, 1994, LEXIS, Nexis Library, News Group File.
[40] *Amgen, Inc. v. Chugai Pharm. Co.*, 706 F. Supp. 94 (D. Mass. 1989). Recombinant erythropoietin is erythropoietin produced by recombinant DNA techniques.
[41] *Amgen I*, at 97.
[42] *Amgen I*, at 96.
[43] *Id*.
[44] *See Id*. at 96, 97 n.5.
[45] *See, e.g.*, Greenfield, *supra* note 36, at 1053 n.14. The court also seemed to recognize the value of Amgen's unique contributions. For example, partly in recognition that "recombinant EPO is an extraordinarily valuable medicine that promises marked relief from renal failure," the court refused on public policy grounds to enter a preliminary injunction against Amgen. *See, e.g.*, *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 13 U.S.P.Q.2D (BNA) 1737 (1989 U.S. Dist. LEXIS 16110, *11) (D. Mass. 1990) [hereinafter Amgen II].
[46] *Amgen I* at 97 n.5, 103-04, 111. For the subsequent case history, see *Amgen II* (magistrate upholding ruling that rEPO infringed patent '195's product claims) and *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir.), cert. denied, 112 S. Ct 169 (1991) [hereinafter Amgen III] (reversing in part by ruling patent '195's invalid but without reversing prior holding that a recombinant protein would infringe a patented isolate derived from natural sources).
[47] Under the patent system, a patent can issue even if an earlier patent cover the same subject area. An inventor may obtain a narrow patent over a subsequent invention but may not have the right to practice that invention if an earlier innovation is deemed sufficiently broad to encompass this subsequent innovation. (For example, a first inventor may obtain a patent over a vessel to hold liquid; a second inventor may obtain a patent over a cup formed by attaching a handle to a liquid holding vessel) In such cases, neither the subsequent nor original inventor will be able to practice the subsequent invention without a license from the other. (In the cup example, neither inventor would be able to practice the cup invention without permission from the other.) *See, e.g.,* Landes & Posner, *supra* note 10, at 317.

[48] Fortunately, the *Scripps* and *Amgen* decisions were eventually resolved privately, through settlements, without adverse effects on the industry. Nevertheless, the potential for great damage exists. Biotechnology is too important an industry for its future to be left to chance.
[49] 35 USC §101; Diamond v. Diehr, 450 U.S. 175, 185 (1981); Parker v. Flook, 437 U.S. 584, 589-92, 594 (1978); Gottschalk v. Benson, 409 U.S. 63, 67 (1972); Gottschalk v. Benson, 409 U.S. 63, 67 (1972); Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); O'Reilly v. Morse, 15 How. 62, 112-121 (1854); Le Roy v. Tatham, 14 How. 156, 175 (1853); Janice M. Mueller, AN INTRODUCTION TO PATENT LAW, 192 (Aspen Publishers, 2003).
[50] Diamond v. Chakrabarty, 447 U.S. 303, 309 (U.S. 1980).
[51] Nevertheless, discoveries of nature would not patentable even if such discoveries are novel and useful. See Chakrabarty, 447 U.S. at 309; Funk Brothers Seed Co., 333 U.S. at 130; Mueller, supra note 49, at 185, 192.
[52] Imagine if someone has a patent to something as basic as electricity. That inventor would then have the power to block all subsequent inventions that make use of electricity. Since the purpose of patents is to incentivize the development of the useful arts, it is not surprising patents over nature, with its great potential to impede development, is traditionally not allowed. See, e.g., also Scotchmer, supra note 4, at 174 (noting given the cost of developing basic scientific innovations is relatively low compared to development of subsequent commercializable applications, the policy not to grant basic, pioneering patents arose mostly from a concern that such patents would chill competition among developers of subsequent applications).
[53] This assertion is by no doubt a settled matter; the role patents should play in the basic sciences and over natural phenomenon continues to be debated today. *See, e.g.,* Scherer, note 9, at 1354-55 (arguing that "the presumption against patenting basic information about natural phenomena might be overcome if … [such patents] served to elicit discoveries that would not otherwise be made or to accelerate the pace at which scientific knowledge advances."); S. A. Rood, "Government Laboratory Technology Transfer: Process and Impact" (Burlington, VT: Ashgate, 2000) (arguing that commercialization of science has lead to broad based inhibition of basic research); E. Campbell, B. Clarridge, M. Gokhale, L. Birenbaum, S. Hilgartner, N. Holtzman, and D. Blumenthal, "Data Witholding in Academic Genetics: Evidecne from a National Survey," 287 J. of the Amer. Med. Assoc. 473 (2002) (interestingly that, even without IP, scientists olften hoard data (and thus inhibiting general research) for private gain).
[54] U.S. Patent 141,072. The yeasts were considered "artificial" under the law because 1.) it required human efforts (in fact painstaking efforts) to extract, and 2.) it, as a collection, allowed fermentation without spoilage, a property which no other colonies of naturally occurring microorganisms conferred. The second claim asserted the isolated "[y]east, free from organic germs of disease, as an article of manufacture."
[55] *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y., 1911).
[56] Parke-Davis, 189 F. 95 at 103 (asserting that "even if [the adrenaline] were merely an extracted product without change … [and thus merely] a purification of the principle, it became for every practical purpose a new thing commercially and herapeutically. That was a good ground for a patent.'')
[57] This is problematic because by treating science as a black box, innovations are be easily mischaracterized (and overly broadly so). At high a level of granularity, all science and technological seem magical. See discussions surrounding infra notes 115-124.
[58] *See Id.* ("The line … is to be drawn … from the common usages of men [rather] than from nice considerations of dialectic.")
[59] *Id.* at 103.
[60] *In re Bergy*, 563 F.2d 1031, 1032, 1035 (CCPA 1977).
[61] Chakrabarty, 447 U.S. at 309-10.
[62] In *Amgen Inc. v. Chugai Pharmaceutical Co*, the district court held that the DNA claims at issue could not have been directed toward the "DNA sequence encoding human EPO since that is a nonpatentable natural phenomenon 'free to all men and reserved exclusively to none.'" Instead, the invention must have been directed toward underlying genetic compounds, "the 'purified and isolated' DNA sequence encoding erythropoietin." Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737, 1959 (D. Mass. 1990). See also "Utility Examination Guidelines," *supra* 63, at 1095 (explaining that "[a] DNA sequence is not patentable because a sequence is merely descriptive information about a molecule.").
[63] The Federal Circuit view genes as "a chemical compound, albeit a complex one…." Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991). The U.S. P.T.O. has pronounced that while "a

DNA sequence itself is not patentable … [a] purified DNA molecule isolated from its natural environment, on the other hand, is a chemical compound and [may be] patentable." Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (Jan. 5, 2001), *available at* http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf.

[64] According to the U.S.P.T.O., a gene is patentable if there is "a specific, substantial, and credible utility for the claimed isolated and purified gene." "Utility Examination Guidelines," *supra* 63, at 1093. According to the PTO, "the utility of a claimed DNA does not necessarily depend on the function of the encoded gene product. A claimed DNA may have a specific and substantial utility because, e.g., it hybridizes near a disease-associated gene or it has a gene-regulating activity." Id. At 1095.

[65] According to the PTO, "an inventor's discovery of a gene can be the basis for a patent [so long as it has been] isolated from its natural state and processed through purifying steps. … An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because … an excised gene … [purified] DNA molecule does not occur in that isolated form in nature…. Patenting compositions or compounds isolated from nature follows well established principles…." "Utility Examination Guidelines," *supra* 63, at 1093.

[66] See Eisenberg, supra note 29, at 786-87, 788-89 (suggesting that the primary motive to patenting genetic materials is for control over the information coded by the molecules); Jackson, note 9, at 11 n. 13 (explaining that "genes are expressions of information, but … the information contained in them is essentially a work of nature (and is valuable mainly because it is broadly found in nature)…."). The reduction of DNA patents into chemical patents is reminiscent of the early practice by which software patents were reduced into specialized hardware patents. See, e.g., In re Pardo, 684 F.2d 912, 916 (C.C.P.A. 1982) (cautiously allowing a software patent on the ground that it was less an abstract algorithm than a set of instructions to control the hardware functions of a computer system). See also, Diamond v. Diehr, 450 U.S. 175, 186-87 (1981)(allowing software patent and distinguishing patent of software as part of complex industrial process from software that produced simple numerical values, which was not allowed).

[67] See Eisenberg, supra 29, at 786-87.

[68] The scope of today's genetic patents are very broad. In denying the suggestion "that DNA patent claim scope should be limited to uses that are disclosed in the patent application," the PTO emphasized, "[a] patent on a composition gives exclusive rights to the composition for a limited time, even if the inventor disclosed only a single use for the composition." "Utility Examination Guidelines," *supra* 63, at 1095.

[69] Diamond v. Chakrabarty, 447 U.S. 303, 309 (U.S. 1980). The USPTO announcement in 1987 that non-naturally occurring nonhuman multicellular living organisms were patentable subject matter under 35 U.S.C. 101. Patent & Trademark Office: Nonnaturally Occurring Non-Human Animals Are Patentable Under 101, 33 Pat., Trademark & Copyright J. (BNA) 664 (1986).

[70] See supra note 64 and 65.

[71] *See* Dan L. Burk & Mark A. Lemley, The Law, Technology & the Arts Symposium: *The Past, Present and Future of the Federal Circuit, BIOTECHNOLOGY'S UNCERTAINTY PRINCIPLE*, 54 Case W. Res. L. Rev. 691, 695-96 (2004).

[72] *Conflicts in Federal Circuit Patent Law Decisions*, 11 Fed. Circuit B.J. 723, 723-34 (2002). *See also*, Duane M. Linstrom, "Spontaneous Mutation: A Sudden Change in the Evolution of the Written Description Requirement as It Applies to Genetic Patents," 40 San Diego L. Rev. 947, 969-70 (2003) (lamenting that "[t]he latest Enzo decision has clarified some issues, but ultimately leaves the 112 written description requirement for genetic patents in a continued state of uncertainty.")

[73] Utility Examination Guidelines, *supra* note 63, 1092-97 (comments 1, 4, 7, 8, 10, 16, and 19). According to the P.T.O., "[i]f a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. … [However,] where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable." Utility Examination Guidelines, *supra* note 63, at 1093.

[74] *See Id*. at 536 ("'(A) patent system must be related to the world of commerce rather than to the realm of philosophy....'").

[75] Brenner v. Manson, 383 U.S. 519, 534-35 (1966) (i.e. an invention where "specific benefit exists in currently available form.")

[76] *Id*. at 521-22, 531-32.

[77] *Id.* at 534 (The court expressed its concern that patents over early stage technologies would "confer power to block off whole areas of scientific development, without compensating benefit to the public.").
[78] *Id.* at 536.
[79] *Id.* at 536.
[80] *See* 51 F.3d 1560 (Fed. Cir. 1995); Mueller, supra note 49, at 161 (discussing how the Federal Circuit has given little attention to *Manson* and has in fact lowered the bar back toward the more lenient pre-Manson "practical utility" standards). *See, e.g.,* Landes & Posner, *supra* note 10, at 306. See also, In re Brana, 51 F.3d 1560, 1567-68 (Fed. Cir. 1995) (clashing with the U.S.P.T.O. over whether the threshold of utility for compounds required FDA approval for clinical trials).
[81] With the ever-decreasing time between research and commercialization and the constantly eroding the distinction between fundamental and applied research, the use of a utility as a subject matter gatekeeper has been deemed even less useful.
[82] See Mueller, supra note 49, at ??
[83] 35 U.S.C. § 112.
[84] See Brenner v. Manson, 383 U.S. 519, 534-35 (1966) (affirming that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility."); Mueller, *supra* note 49, at 65.
[85] *See, e.g.,* In re Angstadt, 537 F.2d at 502 (Enablement requires that "the scope of enablement provided to one of ordinary skill in the art by the disclosure is such as to be commensurate with the scope of protection sought by the claims."); In re Fisher, 427 F.2d 833, 839 (CCPA 1970) ("35 U.S.C. §112 … requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."). To further define what constitutes enablement, the courts have constructed an "undue experimentation" standard: the disclosure must enable a person of average skills in the art to practice the invention without "undue experimentation." *See* In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). The application of the "undue experimentation" standard is fact-specific and can turn on a variety of factors such as how "predictable" or "unpredictable" a technology is. *See* In re Fisher, 427 F.2d at 839.
[86] *See, e.g.,* Eisenberg & Merges, *supra* note 11, at 38 ("The requirement of an enabling disclosure … is justified as a means of ensuring that the public receives its quid pro quo for the patent monopoly."); Mueller, *supra* note 49, at 66 ("The disclosure requirements … effectively implement the *quid pro quo* of the patent system."); In re Angstadt, 537 F.2d 498, 502 (CCPA 1976) ("What is of maximum concern … is whether that disclosure contains sufficient teaching regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and to use the claimed invention.").
[87] Here are a few illustrative cases of how the courts have applied the enablement requirement. In the famous early case of The Incandescent Lamp Patent, the Supreme Court invalided Sawyer and Mann's broad claim over the use of fibrous or textile materials for making incandescent lighting on grounds of enablement. The Incandescent Lamp Patent, 159 U.S. 465 (1895). The Court held that public was not placed "in possession" of the invention because the patent did not detail the specific combination of the materials feasibly needed to make lighting filaments. It would take the later genius and patience of inventors like Edison to accomplish that. Incandescent Lamp, at 474. In another classic case O'Reilly v. Morse, the Supreme Court invalidated Morse's claim for all methods of communicating at a distance over electromagnetic waves. O'Reilly, at 120. Among the requested claims is a claim on "the use of the motive power of … electro-magnetism, however developed[,] for making or printing intelligible characters at any distance." Landes & Posner, *supra* note 10, at 323. While Morse's invention laid the foundation to all sorts of electromagnetic communications, the court held that Morse had only actually demonstrated one of many such methods of applying such communications. *O'Reilly Id*. In a more recent case, the Federal Circuit struck down a patent's broad claims over a biotechnology method involving "antisense" to control the expression of individual genes. Antisense technology is a powerful biotechnology method for controlling gene expression involving complementary DNA sequences. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1366 (Fed. Cir. 1999). The patentee had broadly claimed the application of the technology in eukaryotic and prokaryotic cells even though he was successful in applying the technology to a few cell types. *Id.* At 1372-3. The patent could not be allowed since the "amount of experimentation required to adapt the practice [in reality] … was quite high." Id., at 1372-73.
[88] The Supreme Court pronounced in *Chakrabarty* that "anything under the sun that is *made* by man" (italized added for emphasis) is patentable. Chakrabarty, however, does not explain the post-Charabarty

biotech patenting explosion since it does not define precisely what is meant for something to be "made" by man. The holding of the Court was merely that microorganisms should not be disqualified as patentable subject matter merely by fact of being living organisms as Congress had intended "anything under the sun that is *made* by man" to be patentable. Diamond v. Chakrabarty, 447 U.S. 303, 308-09 (U.S. 1980). It is the liberal notion of human "manufacture" given by the natural extracts doctrine that is ultimately responsible for the post-Chakrabarty patent floodgate. See discussions surrounding supra notes 55-61.

[89] *See, e.g., Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Traditionally, the requirement has been invoked in the context of "time gap" situations such as those involving amendment of claims, the claiming of benefit of another patent application, and interference proceedings. Mueller, *supra* note 49, at 88. For example, whenever changes are made both to the specification and claims of an application, the PTO must reconsider the priority date of each of the claims in light of the history in which new information has been added to the application. The priority date of a claim is the day the PTO is convinced the inventor came "in possession" of the idea expressed. The written descriptions requirement provided PTO a framework to determine when inventor came "in possession" of the each of the ideas expressed. *See, e.g.,* Mueller, *supra* note 49, at 83-84; Gene-Probe Inc., 323 F.3d, at 977-79;Enzo Biochem v. Gene-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002) (Rader, J., dissenting) quoting In re Wertheim, 541 F.2d 257, 191 (CCPA 1976) ("The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him."); Mueller, *supra* note 49, at 84 ("[T]he written description of the invention requirement mandates that the inventor must have been 'in posession' of the claimed invention as of a particular date…."); Eisenberg & Merges, supra note 11, at 44-45 (Under the written description requirement, "the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.").

[90] Regents of UC and Eli Lilly and Co., 119 F.3d 1559, 1567 (Fed. Cir. 1997). Enablement not withstanding, the patentee must also have disclosed "information … pertaining to [the] cDNA's relevant structural or physical characteristics," the enabled disclosure of a "process for obtaining human insulin-encoding cDNA" notwithstanding. *Id.*

[91] *Univ. of Rochester v. G.D. Searle Inc., 358 F.3d 916, 927 (Fed. Cir. 2004).* The patent disclosed a method to identify certain non-steroidal anti-inflammatory compounds that did away with the gastrointestinal side effects (e.g., stomach upset, irritation, ulcers, and bleeding) commonly associated with traditional drugs such as aspirin, ibuprofen, ketoprofen, and naproxen. Id., at 917-918, 929-930. (Fed. Cir. 2004).

[92] *See* Enzo v. Gene-Probe, 323 F.3d 956, 969 (Fed. Cir. 2002) (explaining that "'[t]he purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.'" Even then, the traditional "purpose of the 'written description' [to ensure that the patentee is] … in possession of the invention … merely states a purpose of the written description requirement…. It does not state that possession alone is always sufficient to meet that requirement." In fact, "[a] showing of 'possession' is ancillary to the statutory mandate that '[t]he specification shall contain a written description of the invention,' and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention.").

[93] *See, also,* Eli Lilly & Co., 119 F.3d, at 1566, quoting Fiers v. Revel, 984 F.2d 1164, 1171 (Fed Cir 1993) (An adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention.").

[94] Union Oil Co. of California v. Atlantic Richfield Co., 208 F.3d 989, 997 (Fed. Cir. 2000); see also *Conflicts in Federal Circuit Patent Law Decisions*, *supra* note 72, at 732.

[95] Enzo Biochem v. Gene-Probe Inc., 323 F.3d 956, 971-72 (Fed. Cir. 2002). It is not clear to the author why the Federal Circuit must create an heightened written specifications requirement to address the issue of overly broad claims. 35 U.S.C. §112 already stipulates that each patent "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." If one has already "particularly point[ed] out and distinctly claim[ed]" the as to enable one skilled in the arts to understand the metes and bounds of an invention, why must additional requirements be prescribed to satisfy a judge, jury, or even an inevitably biased expert witness? Since claims are to be interpreted from the perspective of a hypothetical person having ordinary skill in the art (PHOSITA), there

is no reason why the written specifications should not. *See Phillips v. AWH Corp.*, 2005 WL 1620331, *5 (Fed. Cir. 2005) (holding that claim terms are constructed according to "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."); *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1378 (Fed. Cir. 2000) (noting that "our precedent is well-settled that a court will typically limit its inquiry to the way one of skill in the art would interpret the claims in view of the written description portion of the specification."); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986) (explaining that "[a] decision on whether a claim is invalid under § 112 requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification."); Mueller, *supra* note 49, at 41.

[96] *Id.* at 975, *quoting* In re DiLeone, 436 F.2d 1404, 1405 n. 1 (1971). It is unclear to the author why the court is concerned about an inventor not actually reducing to practice C when he had already enabled one skilled in the art to do so. The court has never required a subject matter to be actually reduced in order to be patentable. "To serve as constructive reduction to practice, the disclosure of the subject matter … must meet the requirements of 35 U.S.C. § 112, first paragraph … [, which stipulates that t]he specification shall contain a written description … in such full, clear, concise, and exact terms as to enable any person skilled in the art … to make and use the same…." Bigham v. Godtfredsen 857 F.2d 1415, 1417 (Fed. Cir. 1988). *See, also, e.g.*, *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Educ. and Research*, 346 F.3d 1051, 1055 (Fed. Cir. 2003) (holding that though the "disclosure in an assertedly anticipating reference must be adequate to enable possession of the desired subject matter … [by] the public … [i]t is not, however, necessary that an invention disclosed in a publication shall have actually been made….").

[97] *See* at Enzo Biochem v. Gene-Probe Inc., 323 F.3d 956, 974 (Fed. Cir. 2002)("Perhaps there is little difference in electrical and mechanical inventions between describing an invention and enabling one to make and use it, but that is not true of chemical and chemical-like inventions.").

[98] *Id.*

[99] *See, e.g.,* Scott A. Chambers, "*Written Description" and Patent Examination Under the U.S. Patent and Trademark Office Guidelines*, IP LITIGATOR, Sept.-Oct. 2000, at 9-10 ("Thus, the Federal Circuit's present interpretation of the written description requirement maintains the vitality of the U.S. patent system and provides disclosures that others can build on. By suggesting that disclosure of the structure or actual sequence of complex chemical entities may sometimes be required, the Federal Circuit may have advanced the goal of the patent system to actually put the claimed invention into the hands of the public."); Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1260-61 (2000) ("Without a heightened written description requirement, inventors could receive patent rights to sequences of which they have no knowledge, in organisms with which they have never worked.... Therefore, the Federal Circuit's approach to the written description requirement in the area of biotechnology has prevented nucleotide sequence claims from becoming a Pandora's box that the patent law is unable to control.").

[100] *See, e.g.,* Mueller, Janice M., *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 617 (1998) ("The *Lilly* decision establishes uniquely rigorous rules for the description of biotechnological subject matter that significantly contort written description doctrine away from its historic origins and policy grounding. The *Lilly* court elevate[s] written description to an effective 'super enablement' standard.... [This] will likely chill development."); Mark D. Janis, *On Courts Herding Cats: Contending with the 'Written Description' Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U.J.L. & POL'Y 55, 60, 70, 83 (2000) ("[T]he written description requirement is a threat to the coherence of disclosure doctrines…." "Today … the written description requirement enjoys a prominence wholly out of proportion to its humble origins. … Recent efforts to elaborate the 'possession' standard both confirm the substantial redundancy of the enablement and written description requirements and illustrate the capacity of the written description requirement to serve as a tool for judicial improvisation.").

[101] *See, e.g.,* In re Vaeck, 947 F.2d 488, 495-96 (Fed. Cir. 1991) (In assessing enablement, where claims involve "pioneering," "unpredictable" technologies, "the required level of disclosure will be greater than, for example, the disclosure of an invention involving a 'predictable' factor such as a mechanical or electrical element."); Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1375 n.10 (Fed. Cir. 1999) (In assessing enabelment and "[i]n view of the rapid advances in science, we recognize that what may be unpredictable at one point in time may become predictable at a later time."); See Enzo Biochem, 323 F.3d

(Raider dissent), at 982, ("Beyond mere adequacy of disclosure, [enablement] serves as the line of demarcation between the visionary theorist (adds nothing to the useful arts) and the visionary pioneer (contributes to the useful arts [citations omitted] and also serves to limit claim scope thus demarking the boundary between pioneer inventions and patentable improvements. [citations omitted] The WD [written descriptions] possession test cannot perform these functions.")

[102] History is full of examples where inventors did not originally appreciate the full scope and value of their innovations. In fact, this is one of the benefits of patents: to incentivize disclosure of inventions so their values can be maximized. The original lack of appreciations by the inventors does not by itself limit the contributions actually made to the field (i.e. enabled) and has traditionally not limited the credit attributed to the inventor. Note the "Best Mode" requirement requires a patentee to disclose the envisioned context in which the invention is to be used. The impetus behind this requirement is to improve the quality of the disclosure not to limit the scope of patent.

[103] "[T]he Supreme Court repeatedly cautioned against the disruption of the settled expectations of the inventing community." Enzo Biochem, 323 F.3d (Raider dissent), at 982. "The responsibility for changing [settled law] rests with Congress.... Fundamental alterations in these rules risk destroying the legitimate expectations of inventors in their property." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722, 739.

[104] *See* Janis, *supra* note 100.

[105]An independent requirement raises costs of patent transaction by imposing new additional requirements. The court should also more carefully consider such effects on small entities that can ill afford arbitrary though small rises in patent costs. *See, e.g.,* Gene-Probe Inc., 323 F.3d at 983 (Raider dissent) (The "Lilly/Enzo rule prejudices university or small inventors who do not have the expensive and time-consuming resources to process every new biotechnological invention to extract its nucleotide sequence."); Jackson, note 9, at 21-22 (voicing concerns that patent transaction costs in general disproportionately hurt small entities). In addition, the court should also carefully consider the impact heightened transaction costs on the general incentive to innovate. *See* Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 Berkeley Tech. L.J. 1233, 1262 (2000) ("The primary argument against the Federal Circuit's heightened written description requirement for biotechnological invention is that ... it also 'reduces incentives to invest in innovation by depriving potential patentees of the opportunity to fully benefit from their research.'").

[106]See discussion surrounding supra notes 54-61.

[107] *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). *In re Bergy*, 563 F.2d 1031 (CCPA 1977).

[108] Chakrabarty, 447 U.S. at 309-10.

[109] Chakrabarty, 447 U.S. at 310.

[110] *Id.* at 131.

[111] *Id.* at 130.

[112] For more discussion on appropriate level at which technology should be evaluated, see discussion infra "Evaluation of properties at end user, macroscopic level codifies outdated science."

[113] Just as the innovation in *Funk* was not patentable because it involved only a reshuffling of naturally occurring bacteria, the innovation in *Chakrabarty* would have been unpatentable because it involved merely a reshuffling of naturally occurring genes.

[114] Note that even if no new manufacture is created, the innovation is still valuable and can still be protected. A *use patent* could issue on use of a gene transgenic to confer a specific property to a specific bacteria species.

[115] Cf. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L.REV. 839, 884 (1990) (Urging careful scrutiny over patent scope, especially where great excitement over "new scientific and technological developments" exists, lest monopoly is conferred over an "invention [that] may diverge from 'prior art,' in the sense of actual technological accomplishments, and sweep the market, yet still be only a successful application of knowledge that is apparent to the scientifically sophisticated.").

[116] See discussion surrounding infra notes 175-180, and 228.

[117] Physics, for example, started out as a study of macro phenomenon, but as the field matured, the thrust of it moved to ever-smaller scales. Biology, too, has similarly moved from studying macro phenomenon to studying micro and then molecular phenomena.

[118] See discussions surrounding infra notes 123, 225, and **Error! Bookmark not defined.**.
[119] Novelty, obviousness, enablement would still need to evaluated separately.
[120] See discussion surround supra note 113.
[121] Titanium Metal Corp v. Banner, Fed. Cir, 1985.
[122] The definition of alloys is after all "a substance composed of two or more metals." Webster's third new international dictionary of the English language, unabridged (Springfield, Mass., Merriam-Webster, c1993).
[123] As noted earlier, therapeutic and diagnostic applications often build on many innovations. See supra note 15. To effectively incentivize progress, patents must incentivize each of these innovations. Because many innovations do not make great impacts until combined with other subsequent innovations, patents cannot simply evaluate innovations based on their impact (without disincentivizing these innovations altogether). Rather, the law should evaluate innovations by their contribution to the state of the art instead. Another problem with recognizing innovations by their effects rather than their technological contribution is that the practice tends to over recognize innovations (and thus inevitably impeding future innovations. See discussion surrounding infra note **Error! Bookmark not defined.**). Consider again the case the vitamin deficiency blindness above (in note 15). If patents were to recognize innovations purely by their impact, a patent would be broadly awarded to the person who first successfully uses genetically engineered plants to cure vitamin deficiency induced blindness. However, such a patent would probably over recognize the innovation because at a high enough level of granularity, say from the patient's perspective, the inventor would be credited with broadly inventing a cure to vitamin deficiency induced blindness when all the inventor really did was invent one way of curing the disease. With such broad patents, others who want to create alternative ways of curing the same disease would be blocked from doing so. See also supra note 124.
[124] See also infra note 123.
[125] While PHOSITA is ultimately a judicially manufactured concept, the ideal of PHOSITA is grounded in reality. As Kuhn has noted, scientific and technological fields develop through evolution of paradigms. Thomas S. Kuhn, "The Structure of Scientific Revolutions," (3rd ed., University of Chicago Press, 1996) (discussing how scientific paradigms drive the process of scientific advancements). The dominant paradigm of each field will help inform what is worth pursuing and what the value of each advancement is. Such dominant paradigms will form the conceptual basis of PHOSITA.
[126] This is not such a radical proposition since courts have already traditionally appealed to the fictitious but legally objective PHOSITA standards in other patentability analyses such as obviousness, enablement, and infringement. *See* Burk & Lemley, *supra* note 71, at 709-13. It is noted that asking legally trained professionals to evaluate science and technology accurately can be a difficult proposition. *See* Burk & Lemley, *supra* note 71, at 714-16 (discussing how the Federal Circuit court has gotten the science wrong in continuing to demand a higher stringent disclosure in biotechnology than in other fields); *park Davis.* at 115 (admitting to judge's lack of competence in evaluating accurately technology related issues and specifically urging reforms that would allow courts to "summon[] technical judges to whom technical questions are submitted and who can intelligently pass upon the issues without blindly groping among testimony upon matters wholly out of their ken."). Addressing the problem of requiring the law to evaluate technological innovations accurately, however, is beyond the scope of this paper.
[127] See supra notes 124, 123, and 166.
[128] It is noted that treating different technologies according to different fields, as in metallurgy v. biotechnology, can raise issues of arbitrage as patentee "forum shops" fields of applications to obtain the best patent terms. The patentee may profess that a technology is to be used for one industry when in reality it is used for another. While this may be a problem, it should be noted that patent law, while allegedly uniform in principle, is already non-uniform in application. Burk & Lemley, supra note 138, at 1576-77. Even in applying routine references to PHOSITA (person having ordinary skill in the art), the law already implicitly takes into account the context of the field for which an innovation is to be used.
[129] *See* Merges & Nelson, *supra* note 115, at 903 (concluding that arguments that equate process innovations for product innovations are "not convincing.").
[130] Note this was the fundamental dispute in *Amgen* and *Scripps*. Had the patents in *Amgen* and *Scripps* covered only the purification processes, the recombinant inventors would have been able to practice their inventions without interference from the original extractors. Yet process patents would have aksi incentivized the original analog inventors to make their pioneering process innovations because until the

recombinant processes were developed, their processes would have been the only ones available to extract the products.

[131] Product patents might serve as workable proxies for process patents in certain contexts, particularly where the potential of such patents to block future innovations is low. For example, if there is only one process to extract and manufacture a purified product, the discoverer of that process may be entitled to a product patent. Since product patents are much easier to enforce than process patents, awarding a product patent as a proxy for process innovations make sense in circumstances where such patents would create little blocking costs.

[132] See, e.g., Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95, 97 (U.S. Court of Appeals 1911).

[133] See also supra note 130.

[134] The main challenge to purification is the isolation process, not the formation or stablization of the purified product. The definition of the term "extraction" correctly implies that the product to be purified already exists in nature. Once a product is identified to be the target of extraction, the ultimate product of the purification is predetermined – by nature. The creative part of the innovation is directed at creating the process to produce the product, not in designing a new product.

[135] For a survey of non-utilitarian arguments supporting patents, see, e.g., Wendy J. Gordon, A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property, 102 Yale L.J. 1533 (1993) (presenting philosophical, non-economic perspectives, including those drawn from natural rights, in support of protecting intellectual property).

[136] U.S. Constitution, Art. I, sect. 8, cl. 8. Historical note: the term "Science" in the Constitution actually referred only to copyrightable subject matter. It is the phrase "useful Arts" that correspond to the modern notion of "technologies" and "industries." *See* Mueller, *supra* note 49, at 27.

[137] Graham v. John Deere Co., 383 U.S. 1, 9 (1966). See, also, Fed'l Trade Comm'n, supra note , at 877 ("The PTO functions as a steward of the public interest … to encourage invention, disclosure, and commercial development.").

[138] Dan L. Burk & Mark A. Lemley, "Policy Levers in Patent Law," 89 Va. L. Rev. 1575, 1576 (referring to patents as "our primary policy tool to promote innovation, encourage the development of new technologies, and increase the fund of human knowledge.").

[139] See generally, e.g., Robert Patrick Merges, Patent Law and Policy: Cases and Materials 1-13 (2d ed. 1997) (discussing general patent history and theory); Frank D. Prager, A History of Intellectual Property From 1545 to 1787, 26 J. Pat. Off. Soc'y 711 (1944) (tracing origins of Western patent law); Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. Chi. L. Rev. 1017 (1989) (surveying various theories in support and critique of patents).

[140] A public good is a good that is available to all and where the consumption by one person does not reduce its consumption by another. In economic lingo, their fruits can be enjoyed nonrivalrously. See, e.g., Landes and Posner, supra note 2, at 14. For an introduction to the economic consequences of nonrivalrous goods, see Scotchmer supra note 4, at 34-39.

[141] Note that imitation by itself should not be frowned. America is built on competition and the "[f]reedom to imitate to copy, is a cornerstone of competition." Landes and Posner, *supra* note 2, at 23. It is the effect that externalization of benefit has on the innovation process that is of essence here.

[142] Landes & Posner, supra note 10, at 24, 294 (noting that the "conventional rationale for granting [IP legal protection] is the difficulty that a producer may encounter in trying to recover his fixed costs of research and development when the product or process that embodies a new invention is readily copiable."); Burk & Lemley, *supra note* 71, at 693 (observing that "[l]egal rights in inventions allow inventors to control and profit from goods that are costly to produce, but which are virtually costless to reproduce or to appropriate once they have been created."). The amount by which an innovation suffers the "public good" problem depends on a number of factors, including the ease by which inventions are copied, whether private or public resources are expended, and market conditions that allow innovators to internalize benefits such as high first mover advantage and barrier to entry. Innovations that are not easily copied do not pose a big "public goods" problem because the difficulty of copying ensures that the amount of externalized benefit would not be high. Innovations that the public sponsors, typically through the government, also do not pose a major public good problem since the benefits of public domain technologies ideally accrues evenly back to the taxpaying public. (Whether the taxpaying base would reap the awards equally or whether there would be a net subsidy by one constituency for another is a separate issue.) Similarly, technologies in

markets that offer high first mover advantage and barrier to entry also do not pose big problems because those conditions minimize the amount of externalizationed benefit competitors could achieve.

[143] Only innovations that would not have occurred or be greatly delayed but for patent protections should be protected by patents. It makes no sense to issue patents for inventions that would have occurred even without patents. *See* Landes & Posner, *supra* note 10, at 22, 24. Alternatively, it also would not make much sense to grant a patent in hopes of speeding up an innovation by say one day. This second scenario describes approximately that of genetic patenting. It is probably not wise to use patents to incentivize research where the cost of research is dropping so fast that innovations that the patents allegedly are to incentivize are soon becoming mere routine discoveries. *See* Landes & Posner, *supra* note 10, at 361 (explaining how "excessive investment by those seeking patent protection" become "most wasteful when the cost of making the invention is falling rapidly over time … for then … the making of the invention probably should be deferred.").

[144] Intellectual properties, through the mechanism of licensing, can actually promote competition by shortening current innovation lifecycle and jump-starting future innovations. Scotchmer, supra note 4, at 162. In general, patent monopoly must not be confused with economic monopoly. See Fed'l Trade Comm'n, supra note 186, at 863 "Patents do not necessarily confer monopoly power on their holders, and most business conduct with respect to patents does not unreasonably restrain or serve to monopolize markets." *Cf.* Landes & Posner, *supra* note 10, at 294-95 (observing that the purpose of patents is not just to monpolize, but also to disclose knowledge so that others can be spurred to make further innovations); Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989) ("The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'"); Fed'l Trade Comm'n, supra note 186, at 867 (explaining that barring strong justifications to the contrary, a competitive system should be preferred).

[145] For a proof that disclosure accelerates progress – i.e. that two inventors each innovating independently will lead to faster breakthroughs, where a breakthrough requires at least two sequential inventive steps – see Scotchmer, note 4, at 254-55. See also O'Donoghue, T. 1998. "A Patentability Requirement for Sequential Innovation." RAND J. of Econ. 29:654-916.

[146] *See* Jackson, *supra* note 9, at 7.

[147] *See, e.g.,* Jackson, *supra* note 9, at 7; Scotchmer, supra note 4, at 98; V. Denicolò, "Patent Races and Optimal Patent Breath and Length," J. of Ind. Econ. 44:249-265.

[148] A classic study on the economic impacts of patents is Fritz Machlup, *An Economic Review of the Patent System*, Study No. 15, Subcomm. Pat. Trademark & Copyright, Jud. Comm., 85th Cong., 2d Sess. 9 (1958). Other leading works include: WARD S. BOWMAN, JR., PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL, 15-32 (1973), and F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 379-99 (1970).

[149] Merges & Nelson, supra note 115, at 869-70.

[150] W. Nordhaus, Invention, Growth, and Economic Welfare, 3-15 (1969); Kaplow, The Patent-Antitrust Intersection: A Reappraisal, 97 Harv. L. Rev. 1813, 1855-67 (1984); R. Gilbert & C. Shapiro, Optimal Patent Length and Breadth, 21 Rand J. of Econ. 106 (1990).

[151] Merges & Nelson, note 115, at 843; *see also,* Landes & Posner, supra note 10, at 325 (explaining that beyond the immediate cost benefits of patents, "[b]road patent protection has still another, and fundamental, double-edged effect: it increases the return to the first inventor, which encourages invention, but increases the cost of invention to his successors, which discourages invention."). See also, Suzanne Scotchmer, "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law," 5 J. of Econ. Per. 29 (1991).

[152] *See* Merges & Nelson, supra note 115, at 843.

[153] O'Reilly v. Morse, 56 U.S. 62 (1853).

[154] Note doctrinally, however, that patent law has never acknowledged the need to award an inventor for inspiring the future, no matter how high an impact his insights might prove to be. Patent is to be awarded only for enabled innovations, and Morse did not invent the radio and television. See, e.g.., Beck, The Prospect Theory of the Patent System and Unproductive Competition, 5 Res. L. & Econ. 193 (1983) (arguing that doctrinally, patent law does not protect future innovations enabled by a technology). Nevertheless, telegraphy no also doubt facilitated later telecommunication innovations such as the radio and television. Morse could have really envisioned and helped inspire others todevelop these subsequent

innovations. See Scherer, note 9, at 1361-62 (observing that the enablement requirement allowed innovators to internalizes only part of the benefits of his innovation). Cf. In re Fisher, 427 F.2d 833, 839 (CCPA 1970) (dicussing that "inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on hit teachings. Such improvements, while unobvious from his teachings, are will within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that … the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification…."); Suzanne Scotchmer, "Protecting Early Innovators: Should Second-Generation Products be Patentable?" 27 RAND J. of Econ. 322 (1996), available at http://socrates.berkeley.edu/~scotch/Sc96.pdf (arguing that under some circumstances, the award of broad pioneering patents and withholding of subsequent improvement patents might actually incentivize subsequent innovations).

[155] See Merges & Nelson, supra note 115, at 876.

[156] If the subsequent innovations and applications are truly worthwhile, licensing to enable those technologies should make all parties better off, and hence it is economic suicide for any parties to hold out long enough to defeat the subsequent endeavor. It is in no one's interest to block, and everyone's interest to allow the invention to proceed, provided the tug-of-war to distribute the pie does not unnecessarily break down the process. See, e.g., Scotchmer, supra note 4, at 133-34.

[157] Coase, The Problem of Social Cost, 3 J.L. & Econ. 1 (1960). See, also, e.g., H. Demsetz, Toward a Theory of Property Rights, in 1 Organization of Economic Activity 104, 112-13 (1988) (discussion of efficient bargaining of licensing and assignments to redistribute patent rights after patents are granted); Clark, Major & Mollett, The Development and Implementation of New Zealand's ITQ Management System, in Rights Based Fishing 191, 196 (P. Neher, R. Arnason & N. Mollett eds. 1989) (concluding that the market for randomly-allocated "Individual Transferable Quotas" in a fish stock management system would lead to efficient allocation through subsequent trading of rights among firms); Merges & Nelson, supra note 115, at 876.

[158] See Merges & Nelson, supra note 115, at 12-14 (discussing how contractual transactions can help to attain optimal use and investment of properties).

[159] See Scherer, *supra* note 9, at 1362 (observing that the determination of "the division of rents between the original discoverer and follow-on developers requires bargaining, and solutions may materialize that either stalemate further progress or undermine incentives for additional private investment in basic discovery."); R. Cooter & T. Ulen, Law and Economics 105 n.15 (1988) (discussing how the initial distribution of property rights can affect the ultimate level of output despite subsequent trading of rights among bargaining parties.). One interesting proposal to reduce information asymmetry may be to assign a duty to patentees to make use of the patent. This ensures that patentees are involved in the process of making active use of the patents. When patentees are so involved, the risk of large information assymetry between the patentee and potential licensee should be drastically reduced.

[160] See, e.g., M.A. Heller & R.S. Eisenberg, "Can Patents Deter Innovaiton? The Anticommons in Biomedical Research." Science 280:698-701 (discussing the so called "anticommons" problem where because of the lack of a natural benchmark to establish how profit between original and subsequent innovators are to be distributed, the bargaining between those innovators to facilitate latter applications can break down); Scotchmer, note 4, at 135-37 (noting, for example, that it is important to divde profits in proportion to the actual costs expended by each inventor); id. at 131 (noting that "intellectual property is a blunt instrument for [this] delicate problem"); J.R. Green & S. Scotchmer, "On the Division of Profit in Sequential Innovation," 26 RAND J. of Econ. 20 (1995), available at http://socrates.berkeley.edu/~scotch/Gr_and_Sc.pdf.

[161] Rent seeking often arise from information asymmetry. A deal breaks down because the parties assign irreconcilable value or expectations regarding a follow-on innovation. For example, entrenched innovators may wish to prolong a previous generation of technologies at the expense of new entrants even though new entrants might bring in more revenues to the original innovators in terms of license royalties. See, e.g., Scotchmer, note 4, at 147-48. Parties may also be looking to game each other. *See, e.g.,* Landes & Posner, *supra* note 10, at 320-21.

[162] *See* Landes & Posner, *supra* note 10, at 321 (discussing how monopoly leads to complacency and information asymmetry, which ultimately increases transaction costs of licensing.).

[163] The *Scripps* and *Amgen* cases discussed earlier provide two prime examples, where overly broad patents threaten to impede subsequent innovations. Patent pooling and consolidations constitute potential

remedies. See, generally, T. O'Donoghue, S. Scotchmer, and J. F. Thisse, "Patent Breath, Patent Life and the Pace of Technological Progress," 7 Journal of Economics and Management Strategy 1 (1998); J. Lerner & J. Tirole, "Efficient Patent Pools," 94 American Economic Review 691 (2004). On the other hand, patent pools pose unique problems of their own. See, e.g., J. H. Barton, "Reforming the Patent System," 287 Science 1933 (2000) (explaining how patent pools can dilute incentives to innovate); S. Graham, B. H. Hall, D. Harhoff, and D. Mowery, "Patent Quality Control: A Comparison of U.S. Patent Re-examinations and European Patent Oppositions," in W. Cohen and S. A. Merrill, eds., *Patents in the Knowledge Based Economy*, 74-119 (Washington, D.C.: National Academies Press, 2003) (discussing how patnet pools can serve as barriers to new comers in the innovation process); H. Hovenkamp, M. Janis, and M. A. Lemley, "Anticompetitive Settlement of Intellectual Property Disputes," 87 Minn. L. Rev. 1719 (2003) (discussing how patent pools can reduce competition in the market place); C. Shapiro, "Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting," 1 Innovation Policy and the Economy 119, 139 (2001) (raising various issues regarding patent pools and joint licensing schemes, such as whether pools should be allowed where less restrictive mechanisms such as cross-licensing exist to unlock blocking patents and hence allow for additional competition in the marketplace); Scotchmer, supra note 4, at 176-77 (noting that pools that in general consist of complementary technologies create real value and hence are usually good while pools that consist generally of technological substitutes create few values other than creating artificial market monopolies and hence are usually bad).

[164] There has not been a lot of schlarly writings on patent scope. A few notable exceptions include: McFetridge & Rafiquzzaman, The Scope and Duration of the Patent Right and the Nature of Research Rivalry, 8 Res. L. & Econ. 91 (1986); Gilbert & Shapiro, supra note 150; Scherer, Nordhaus's Theory of Optimal Patent Life: A Geometric Reinterpretation, 62 Am. Econ. Rev. 422 (1972); J. Shoven, Intellectual Property Rights and Economic Growth, in Intellectual Property Rights and Capital Formation in the Next Decade 46, 49-50 (1988):

[165] Broad patents are patents with scope broader than the enabled innovation. Narrow patents are patents whose scopes are narrowly tailored to be coincident with the enabled innovation.

[166] Cf. Landes & Posner, supra note 10, at 294 (observing that for patents to efficiently incentivize innovations, patent scopes should be coincident with the amount that the disclosures enable a person skilled in the arts to practice the invention).

[167] In economic terms, prospecting works by internalizing related or follow-on benefits. As discussed earlier, broad patents may more fully compensate pioneers by helping pioneer innovators better internalize follow-on benefits. See discussions surrounding supra note 154.

[168] Kitch, The Nature and Function of the Patent System, 20 J.L. & Econ. 265, 276-77 (1977).

[169] Cf. Landes & Posner, supra note 10, at 13 (describing how broad patents "enables people to reap where they have sown. Without that prospect the incentives to sow is diminished.").

[170] Kitch, supra note 168, at 276-77.

[171] See Kitch, supra note 168, at 279; Dasgupta, Patents, Priority and Imitation or, The Economics of Races and Waiting Games, 98 Econ. J. 66 (1988) (exploring conditions where waiting is more profitable than joining patent races); Katz & Shapiro, R & D Rivalry with Licensing or Imitation, 77 Am. Econ. Rev. 402 (1987) (exploring the costs and benefits of inventing around v. licensing);

[172] Id. See also N. Gandal & S. Scotchmer, "Coordinating Research through Research Joint Ventures," 51 J. of Pub. Econ. 173 (1993) (exploring how firms can cut down the cost of innovation by delegating specific follow up research to efficient firms); I. Brocas, "Optimal Regulation of Cooperative R&D under Incomplete Information," 52 J. of Ind. Org. 81 (2004) (discussing how patents promote more sharing of information than in a competitive marketplace); Tandon, Rivalry and the Excessive Allocation of Resources to Research, 14 Bell J. Econ. 152 (1983) (analogizing invention races to fishing races in a pool, where "overfishing" result when too many people seek develop the same inventions).

[173] See Kitch, supra note 168, at 271-75.

[174] *See, e.g.,* Kitch, supra note 168, at 285-87.

[175] This seems almost too intuitive to have to assert.

[176] Consider a broad patent that gives the right to A, B, and C in return for only the development of A. Normally, rational parties would spend only up to the (risk adjusted) value of A to develop A. However because of the legal generosity, many would now spend up to the value of A, B, and C to develop just A. Over-incentivization is not socially desirable because it is occurs when the society has *overpaid* for an

innovation. Over-incentivization occurs when the amount if the average monopoly rent exceed, after factoring risk-adjusted interest cost adjustments, the cost of R&D. *See* Scherer, *supra* note 9, at 1350.

[177] *See* Scherer, *supra* note 9, at 1360 (describing how R&D activities, like any other activities, exhibits a diminishing rate of returns); Tim Hubbard and James Love, "A New Trade Framework for Global Healthcare R&D," 2 PLoS Biology 147, 150 (describing how increased patent incentives have incentivized R&D of "diminishing returns"); Landes & Posner, supra note 10, at 17-18, 322, 328 (discussing how R&D races that produce premature technologies with no immediate application actually constitute a net social loss). As low hanging fruits of research opportunities are picked, any additional resources poured into the area must be used to conduct ever increasingly expensive and speculative research. *See* Scherer at 1360. Alas, doubling the amount of cancer research funding, for example, would not necessarily halve the time to a cure.

[178] Patent races are the mirror image of competitive waste, with one an inherent result of broad patents and the other an inherent result of narrow patents. Cf. Wright, The Resource Allocation Problem in R & D, in The Economics of R & D Policy 41, 49-56 (G. Tolley ed. 1985) (discussing the economic similarity between the general common pool model, which leads to competitive waste as multiple parties compete to make the same follow-on innovations, and the so-called "race" models, where multiple parties compete to make the same early pioneering innovation to attempt to corner a market).

[179] All activities, including R&D, incur opportunity costs (in a world with limited resources). Broad patents incentives encourage the deployment of resources that could be better spent elsewhere to develop speculative or premature technologies. See supra note 177.

[180] When law over recognizes innovations, it prematurely recognizes related and follow-on innovations tobe invented when they have not been. When those innovations finally take place, the law would not recognize them as innovations since it had believed those innovations to have already taken place. This could happen, for example, if the law under-appreciates the prior art, leading to patent races and competitive waste in the innovation generating process. See, e.g., Scotchmer, supra note 4, at 46. See also discussion surrounding supra notes 176-192.

[181] Some have suggested that patent incentives for biotech is not over-incentivized since the profits of U.S. biotech and pharmaceutical industry approximates that of other industry averages. However, this is incorrect because it is not possible to determine whether patents are over-incentivizing or under-incentivizing an industry simply by examining the industry's average returns. As Landes & Posner has also noted, "competition for monopoly rents will … tend to transform them into costs without necessarily producing commensurate social benefits." Any extra profits in an industry would simply be spent on progressively more fancy infrastructure (such as marketing) or on successively more speculative research until the aggregate return of the entire industry reverses back to levels comparable with other industries. *See* Lands & Posner, *supra* note 10, at 315. Similarly, as George Stigler has observed regarding the costs of patenting, "the prospects of monopoly pricing will lead to such a scale of investment in producing knowledge that it will return only the competitive rate of return on average." George J. Stigler, "A Note on Patents," in Stigler, *The Organization of Industry* 123, 124 (1968).

[182] See discussions surrounding supra note 127.

[183] Patents are not awarded for innovations that the technological community finds important but that the law mistakenly deems unimportant. This can happen, for example, if the law over-appreciates the prior art, prematurely recognizing innovations that had actually not been made. See infra note 180. The problem with under-incentivization is that too little competition and resources are invested in the innovation generating process. See, e.g., Scotchmer, supra note 4, at 46.

[184] See discussions surrounding supra note 85.

[185] Kitch might not have fairly accounted for the benefits of broad patents. Broad patents may only move competitive waste from latter to earlier rounds of the innovation life cycle. See discussions surrounding infra note 191. The magnitude of "competitive waste" in the competition for follow-on innovations may also not have been as great as Kitch envisioned. *See* Landes & Posner, *supra* note 10, at 301 (observing that "the research expenditures by the losers of the race may not be wasted … for the expenditures will generate information that the losers may be able to use in other projects.").

[186] See Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 156 (1989) (the Supreme Court stating that "free competition" is "the baseline" on which "the patent system's incentive to creative effort depends."); Fed'l Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, A Report by the Federal Trade Commission (October 2003), 1, available at http://

www.ftc.gov/os/2003/10/innovationrpt.pdf ("Competition through free enterprise and open markets is the organizing principle for most of the U.S. economy. Competition among firms generally works best to achieve optimum prices, quantity, and quality of goods and services for consumers."); id. at 882 (While "[t]here is broad consensus on the significant role that … patents can play to spur innovation and to encourage the disclosure and commercial development of inventions … [t]he importance of competition as a spur to innovation also should be recognized."); Merges & Nelson, note 115, at 843-44.

[187] See U.S. Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (Washington, DC: Department of Justice and Federal Trade Commission, 1995) (arguing, inter lia, that concentrations of market power tend to reduce competition to innovate and retard progress); Merges & Nelson, supra note 115, at 877 (arguing that "rivalry facilitates technical advance and unified control damps it"); supra note 186; K. Arrow, "Economic Welfare and the Allocation of Resources for Invention," in R. Nelson, ed., *The Rate and Direction of Economic Activities: Economic and Social Factors*, 609-626 (National Bureau of Economic Research Conference Series, Princeton, NJ: Princeton University Press, 1962). For an interesting counter point, see Joseph Schumpeter, "Capitalism, Socialism and Democracy," (New York: Harper & Row, 1942) (arguing that large, monopolistic firms with access to deep resources are more innovative than small, resource-strapped start up companies). For a balanced discussion of both perspectives, see R. Gilbert & G. C. Sunshine, "The Use of Innovation Markets: A Reply to Hay, Rapp and Hoerner," 64 Antitrust L. J. 75 (1995); R. Gilbert & G. C. Sunshine, "Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets," 63 Antitrust L. J. 569 (1995).

[188] Competition, by involving more parties throughout the innovation process, can help to reduce instances of IP hold ups simply by increasing the number of stakeholders with important IP. See discussions surrounding infra notes 204-207. Competition also incentivizes parties to participate longer in an innovation process by preserving plenty of opportunities for many to compete throughout the innovation life cycle. By incentivizing stakeholders to stay longer in an innovation process, competition help to bridge information asymmetry gaps among IP stakeholders as participants share similar views about the technologies than non-particants, which can reduce the transaction costs of IP usage in general.

[189] Concentrating competition for patents toward the earliest phases of an innovation life cycle where there is most uncertainty can foster wasteful speculation. Distributing competition throughout the process enables competing patentees to pursue innovations at more rational and opportune stages. See discussions surrounding infra note 191; Merges & Nelson, *supra* note 115, at 883-84, 903 (1990) (noting that patent scope need to be carefully scrutinized in science-based industries because "scientific developments tend to narrow and focus perceived technological opportunities…[where] it is anticipated that the first to apply a scientific finding will get a patent of considerable scope.").

[190] See discussion surround supra note 172.

[191] *See* Landes & Posner, *supra* note 10, at 319-20, 324 (explaining how increasing patent scope may simply shift the patent race (for a broader patent) to an earlier period); id. at 202; supra note 178. For Kitch's response, see Kitch, Patents, Prospects, and Economic Surplus: A Reply, 23 J.L. & Econ. 205, 206 (1980).

[192] With broad patents, an early legal "win" can enable inventors to corner an entire field.

[193] *See* Merges & Nelson, *supra* note 115, at 874-75

[194] In an uncertain environment, when even pioneers can rarely predict the future direction of technologies they help to invent (see infra note 195), coordination makes little sense. Why designate a party to coordinate when no party is in a good position to foresee the future.

[195] Here are some notoriously embarrassing past predictions about the future: "I think there is a world market for maybe five computers" (Thomas Watson, Chairman of IBM, 1943); "While a calculator … [today] is equipped with 10000 vacuum tubes and weighs 30 tons, computers of the future may have only 1000 vacuum tubes and weigh only 1.5 tons." (Popular mechanics, 1949); "I have travelled the length and breadth of this country and talked with the best people, and I can assure you that data processing is a fad that won't last out the year" (Editor in charge of business books for Prentice Hall, 1957); "But what... is it good for?" (Engineer at the Advanced Computing Systems division of IBM, commenting on the microchip, 1968); "There is no reason why anyone would want a computer in the home" (Ken Olson, Present, Chairman and founder of Digital Equipment Corporation, 1977); "640K should be enough for anybody" (Bill Gates, CEO of Microsoft, 1981).

[196] After all, U.S. patent law, at least in principle, apply uniformly to all fields. See Dan L. Burk, "Policy Levers in Patent Law," 89 Va. L. Rev. 1575, 1576 (2003). (noting that "[w]ith only a few exceptions, the statute does not distinguish between different technologies in setting and applying legal standards."). Cf. id at 1577 (noting however that "[a] closer examination of patent law demonstrates that it is unified only in concept. In practice the rules actually applied to different industries increasingly diverge.")

[197] See Burk, id., at 1577 (concluding that "there is no reason to assume that a unitary patent system will optimally encourage innovation in the wide range of diverse industries that it is expected to cover."). For arguments touting the benefits of applying patent law differently based on the technologies and fields involved, see Richard C. Levin et al., "Appropriating the Returns from Industrial Research and Development," *Brookings Papers on Economic Activity* 783 (1987); Mark Schankerman, "How Valuable Is Patent Protection? Estimates by Technology field," 29 *RAND Journal of Economics* 77 (1998); Robert Mazzoleni and Richard R. Nelson, "The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate," 27 *Research Policy* 273, 275-76 (1998); Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, "Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)" (National Bureau of Economic Research Working Paper No. 7552, 2000). Quotes from http://www.mth.uct.ac.za/digest/pcquotes.html.

[198] Merges & Nelson, supra note 115, at 880, and more specifically at 884-916.

[199] See Merges & Nelson, supra note 115, at 880 (introducing the concept of the "discrete invention model" where "an invention is discrete and well-defined, created through the inventor's insight and hard work … [where generally] the invention does not point the way to wide ranging subsequent technical advances … [or] define any broad prospect.").

[200] Merges & Nelson, supra note 115, at 882 (describing how a "new chemical product is in most cases a discrete entity … like penicillin"), 897 (describing how "chemical product invention tends to fit the 'discrete invention' model.").

[201] For a more comprehensive of the dynamics involved in fields with discrete innovations, see, e.g., Nancy Gallini & Suzanne Scotchmer, "Intellectual Property: When Is It the Best Incentive System?" in "Innovation Policy and the Economy" 62-65 (Vol 2, Adam Jaffe, Joshua Lerner and Scott Stern, eds, MIT Press), available at http://socrates.berkeley.edu/~scotch/G_and_S.pdf.

[202] See Merges & Nelson, supra note 115, at 880-81 (observing that in *discrete invention* industries, "possession by [a] firm of a proprietary lock on the invention is not a serious hindrance to inventive work by many other firms.")

[203] Many product-based industries are of this type since most products transcend and depend on a wide diversity of technologies. Cf. Scherer, note 9, at 1363 ("A National Science Foundation–backed study of the scientific and technological ''events'' that led to five new technologies, including the first oral contraceptive pill, demonstrated the large number of research streams that had to converge to yield ultimate practical embodiments.68")

[204] See Scherer, supra note 9, at 1363 (discussing the problem of rent seeking faced by barge owners when operating along different sections of the Rhine River managed by multiple toll operators); Scotchmer, supra note 4, at 132 (discussing how blocking patents can lead to grid lock and how innovating stakeholders holding out to seek maximum royalties can stifle subsequent research).

[205] For more details on the complex dynamics of IP licensing in fields with mutually dependent, cumulative spheres of inventions, see generally, e.g., Gallini & Scotchmer, supra note 201, at 65-69.

[206] *See* Gallini & Scotchmer, supra note 201, at 71-72 (observing that "the optimal design of the property right should depend on whether firms contract with others for the use of their protected innovations. With fluid contracting, policies that otherwise would be inefficient may be optimal."); Wesley M. Cohen, *Patents: Their Effectiveness and Role* (slides prepared for the FTC/D'oJ Hearings on Competition and Intellectual Property Law in the Knolwedge-Based Economy, Feb. 20, 2002 to summarize a recent Carnegie-Mellon survey of R&D laboratory managers on the effectiveness of patents in stimulating innovation) 14, *available at* http://www.ftc.gov/opp/intellect/cohen.pdf (visited April 9, 2005) (observing how in industries where it few firms own all the patent rights in a particular product (e.g. a computer chip), firms are mutually dependent and more amicable to cross-licensing.).

[207] Henry S. Rowen, "Serendipity or Strategy, How Technology and Markets Came to Favor Silicon Valley" in "The Silicon Valley Edge," 190.

[208] This is not surprising because as Coase and other economists have theorized, the distribution of initial property rights (patent rights) should not adversely affect the ultimate distribution of rights if the

transaction cost can be minimized (which firms, forced by mutual dependence, have). *See, e.g.,* Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089 (1972) (discussing the implication of Coase in a zero-transactional-cost setting); supra discussion surrounding supra note 157.

[209] Breakthrough-based industries are sometimes young industries which, as the industry matures, evolves to become mutually dependent, cumulative industries described above. See Merges & Nelson, *supra* note 115, at 908 (1990).

[210] Merges & Nelson, *supra* note 115, at 907 (1990).

[211] Merges & Nelson, *supra* note 115, at 884, 915 (noting that in science-based industries, "there is a real danger that allowing patent scope to be overbroad may enable the individual or firm who first came up with a particular practical application to control a broad array of improvements and applications" and emphasizing "the dangers of awarding overly broad patents early in the history of an industry founded on recent scientific advances.").

[212] Rarely is one single pioneer expected to corner the effort of follow-on developments in science-based industries. See Landes & Posner, supra note 10, at 319 (noting that, partly because the future of technologies are so hard to predict, even the "original prospector may have a flawed conception of the optimal path of development."). In science-based industries, the rapid speeds at which breakthrough innovations develop further argues for allowing multiple parties to participate in follow-on developments as the diversity of expertise and the resources needed can be quite substantial.

[213] The cumulative nature of science-based endeavors is clearly implied by Einstein's famous "on the shoulder of giants" comment. Most important technologies outside of traditional pharmaceuticals and chemical industries fits the cumulative model. See Scotchmer, supra note 4, at 134.

[214] In cumulative, mutually dependent industries, the creators of technologies are also consumers of technologies, forming a relationship of dependence that is symmetric (mutual) among stakeholders. In science-based industries, the creators (e.g. research institutes) and consumers of technologies (e.g. device manufacturers) are usually distinct entities. See Scherer, note 9, at 1363 ("In biotechnology, the asymmetry of relevant actors' positions—ranging from university scientists through genome-researching firms, vector providers, and instrumentation makers to specific biopharmaceutical developers—is likely to make it more difficult to find a sufficient community of interest to organize comprehensive low-royalty cross-licensing."). The dependence between stakeholders in science-based industries are thus often not symmetric. See Scotchmer, supra note 4, at 131-32.

[215] Scherer, note 9, at 1362 ("Bargaining stalemates are especially likely when the discoverer of A has broad rights covering follow-on developments, but when A, like many basic scientific discoveries, has little or no commercial value by itself"). See also, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anti-Commons in Biomedical Research*, 208 Science 698, 698 (1998).

[216] As Coase has noted, if transaction costs cannot be ignored, the initial distribution of property rights becomes of paramount importance to subsequent efficient utilization of property. *See* THRA'INN EGGERTSSON, ECONOMIC BEHAVIOR AND INSTITUTIONS 104-05 (1990) (recognizing that "Coase's main contribution … was to arouse our awareness of positive transaction costs."); ROBERT COOTER & THOMAS ULEN, LAW AND ECONOMICS 105 n.15 (Boston, Pearson Addison Wesley, 1988).

[217] *See, e.g.,* Frederic M. Scherer, *Nordhaus's Theory of Optimal Patent Life: A Geometric Reinterpretation*, 62 AM. ECON. REV. 422 (1972); WILLIAM D. NORDHAUS, INVENTION, GROWTH, AND ECONOMIC WELFARE (MIT Press, Cambridge, 1969).

[218] Evidence tauting both the effectiveness and ineffectiveness of patents abound. *See, e.g.,* Mueller, *supra* note 49, at 23; Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 737 (1990). (discussing how "[w]hile the patent system is often justified as a means of providing incentives to invest in socially valuable research and development, there are no clear answers to the empirical questions of when these incentives are needed, or how strong the incentives should be to have an optimal impact on behavior."); Yali Friedman, Ph.D., "Could Patents have Sped Penicillin Development?" *available at* http://biotech.about.com/library/weekly/aa_penicillinpatent.htm (discussing how one researcher's decision not to patent monoclonal technologies and another's to patent recombinant DNA technologies both facilitated the rapid developments of follow-on technologies.); Richard Levin, Alvin Klevorick, Richard R. Nelson, and Sidney Winter, *Appropriating the Returns from Industrial Research and Development* in BROOKINGS PAPERS ON ECONOMIC ACTIVITY: MICROECONOMICS (Washington, 1987), 783–820 (in the so-called "Yale University survey," finding that managers rank patents as the second least effective method

for protecting the competitive advantages of new products and processes); Wesley J. Cohen, Richard R. Nelson, and John P. Walsh, *Firms Patent (or Not)*, (working paper, Carnegie–Mellon University, January 2000), *available at* http://papers.nber.org/papers/w7552.pdf and http://www.dklevine.com/archive/cohen-survey.pdf (following up Levin's study in a more extensive Carnegie-Mellon survey in 2000, finding that managers rank patents as the second least effective methods for appropriating innovation value); Mariko Sakakibara and Lee Branstetter, "Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Law Reforms," 32 *RAND Journal of Economics* 77, 98-99 (2001) (recent study of Japnese patents finding that despite Japan's expansion of patent rights since 1988, there has been no effect on innovation or R&D).

[219] See Merges & Nelson, note 115, at 843.

[220] See Merges & Nelson, note 115, at 843-44, 908-09. Also, since broad patents tend to focus competition early while narrow patents tend to spread competition throughout (see discussions surrounding supra notes 190-192), in industries where significant follow-on resources or risk taking are required, patents should be kept narrow so patent incentives and competition can be preserved for as many stages of innovations as possible. See discussions surround note 246.

[221] Merges & Nelson, note 115, at 844 (warning – after examining follow-on innovation patterns in industries as diverse as electric lighting, automobile, airplane, semiconductors and computers, and pharmaceuticals – that "[i]n many industries the efficiency gains from the pioneer's ability to coordinate are likely to be outweighed by the loss of competition for improvements to the basic invention.").

[222] Some have suggested that the solution to broad patenting is to practice narrow claim constructions. See, e.g., Scherer, note 9, at 1364. However, if the problem of overly broad patents can be fixed relatively easily by simply evaluating the underlying innovation with technical competence, it would seem more efficient to solve the problem at the source than fixing the problem later.

[223] See discussions surrounding supra note 175.

[224] See discussions surrounding supra notes 175-180.

[225] The sequencing of the human genome is but a first step on the road toward many awe-inspiring biotech applications. Next up is the identification of the functional role of genes: how genes regulate each other and how genes direct a complex web of biological processes. Because genes regulate and serve as the templates of all biochemical processes, researchers hope that genetic insights will translate to insights into all aspects human biology, including the etymology of diseases, including cancers.[225] Diagnostic and therapeutic applications will likely arrive after solid progress in these area and also most likely in rounds. The first application will probably consist of diagnostic techniques that foster early detection. The second might involve innovative drugs that effectively kill targeted cancer cells. Later waves of innovations might involve some sort of cure for cancer altogether.

[226] When patents over-incentivize in one round, they will have to under-incentivize in another round. See discussions surrounding supra note 180. Overly focusing in any one round is not desirable especially since it is impossible to know *a priori* which rounds would yield the most critical innovations, if there are even such rounds.

[227] See supra note 123.

[228] Biotechnological innovations and applications often build on multiple prior innovations, which can increase transaction costs by exacerbating rent seeking problem such as hold ups. See supra notes 15, 123, and 204.

[229] See discussions surrounding supra notes 199-202.

[230] Genes are template instructions that direct all life processes. Gene sequences by themselves, however, are useless. It is the insights into and control over those life processes that will enable all the great future biotech innovations envisioned today. Genomic maps are important, but they constitute really just a roadmap to future discoveries. See discussions surround supra note 225; Matthew Herper, "Genome Scientists: Gene Patents Are Bad," Forbes (2/26/2002), available at http://www.forbes.com/2002/06/26/0626targets.html (quoting Craig Ventur, a famous biologist who has himself taken out many gene patents, admitting that "[b]locking another biotech or a pharmaceutical company from trying to come up with a cure for disease really does block research and the public loses. Why should one company say that's their unique source of biology?"); M. K. Cho, Preparing for the Millennium: Laboratory Medicine in the 21st Century, 47-58 (AACC Press, Orlando, FL, ed. 2, 1998); J. F. Merz, A. G. Kriss, D. G. Leonard, M. K. Cho, 415 Nature 577 (2002); 3. E. G. Campbell et al., 473 JAMA 287 (2002); L. B. Andrews, 803 Nature Rev. Genet. 3 (2002) (all four articles noting that the impact of

gene patents on scientific research and medical care can be especially severe because there are no alternatives to a patented gene in diagnosis, treatment, and research); Jackson, note 9, at 20 (noting that genetic workarounds are practically impossible especially when the practice of patent portfolio and thickets are incorporated).

[231] See discussions surround supra note 208.

[232] See discussions surrounding supra notes 214-215.

[233] For example, broad pharmaceutical patents are awarded not just to cover the technological risks with developing the drugs, but also the regulatory risks associated with a long FDA approval process and market risks associated with potential competing therapeutic solutions over a long horizon.

[234] For a summary of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights, see http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#nAgreement. For a recent discussion framing the issues raised by the agreements, see "Access to Medicines Intellectual property protection: impact on public health," 19 WHO Drug Information 236 (2005).

[235] Pharmaceutical innovations typically involve two simultaneous types of innovations: 1.) an innovation over the discovery of a drug target – i.e. the use of a naturally occurring compound to obtain a particular therapeutic effect; 2.) an innovation over the process to manufacture or isolate a compound with a specified threshold of purity. A patent over the use of a compound for a specified therapeutic effect (perhaps also with a specified threshold of side effects) would provide ample protection over drug companies'drug target discovery efforts as well as drug companies' FDA and marketing investments. A patent over the manufacturing process would provide ample protection over drug companies' efforts to innovate industrially processes that produce naturally compounds of a claimed purify.

[236] This has been safely done in industries with relatively independent spheres of innovations such as traditional pharmaceutical industries. Cf. discussion surrounding supra notes 199-202.

[237] For a good overview of various incentives to promote technological progress, see generally, e.g., Stephen M. Maurer and Suzanne Scotchmer, "Procuring Knowledge" in "Intellectual Property and Entrepreneurship: Advances in the Study of Entrepreneurship, Innovation and Growth" (Vol 15, pp. 1-31. The Netherlands: JAI Press (Elsevier), edited by Gary D. Libecap, 2004), available at http://socrates.berkeley.edu/~scotch/prizes.pdf.

[238] For hundreds of years, scientific progress has been incentivized by science-based incentives such as recognition, prestige, and a desire to contribute to humanity. While the recent commercialization of science has blurred the boundary between science-based and patent-based incentives somewhat, the power of science-based incentives remains strong. *See* John M. Golden, "Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System," 50 Emory L.J. 101, 110 (observing that "even in the present age of 'entrepreneurial science' and even within industry itself, the values and incentives that motivate biotechnology researchers tend to be closer to the 'public sector values' associated with university-based science than to the values associated with a market-oriented focus on maximum financial profit."); Landes & Posner, supra note 10, at 306-07 (observing "[i]n effect, basic research is incentivized by a reward system that involves prestigious academic appointments, lecture fees, grants that reduce teaching loads, and the prospect of Nobel and other prizes while applied research … is incentivized by intellectual property rights.").

[239] *See* Zvi Griliches, Ariel Pakes, and Bronwyn H. Hall, "The Value of Patents as Indicators of Inventive Activity," in *Economic Policy and Technical Performance* 97, 120 (Partha Dasgupta and Paul Stoneman eds. 1987) (finding that "while the aggregate value of patent rights appears to be quite high, it is estimated to be only on the order of 10 to 15 percent of total national expenditures on R&D. Hence it is unlikely to be the major factor in determining the overall level of [innovations]."); F.M. Scherer, Industrial Market Structure and Economic Performance 447 (2d ed. 1980) (describing under what conditions firms may find investment in innovation profitable even without patent protection).

[240] See discussions surrounding supra notes 228-232.

[241] See, e.g., supra notes 186 and 144.

[242] *See* Merges & Nelson, *supra* note 115, at 873-79; Richard R. Nelson & Sidney G. Winter, *Evolutionary Theorizing in Economics*, 16 J. ECON. PERSPECTIVES 23, 33-39 (Spring 2002). *See also generally* RICHARD R. NELSON & SIDNEY G. WINTER, AN EVOLUTIONARY THEORY OF ECONOMIC CHANGE (Cambridge, Massachusetts, Belknap Press of Harvard University Press, 1982).

[243] See supra note 194 and 195. In endeavors where the impediment to innovations is resource deficiency not scientific uncertainty, central command might make sense, as in the case of the Manhattan project

where the government took command of the development of the nuclear bomb. Rowen, supra note 18, at 186 (noting that "[t]here are circumstances in which central control of technology is appropriate, indeed essential, as in the Manhattan Project during World War II or the race to the moon. But the record shows that when there is rapid technological change, as in the computer industry, and much uncertainty about which of many possible paths will be successful, a decentralized system in which many ventures are tried is more likely to succeed than a centralized one.")

[244] The skillset needed for developing pioneering and follow-on innovations can be very diverse. *See, e.g.,* Scherer, *supra* note 9, at 1362 ("[T]he kinds of competence needed for follow-on work may be quite different from what was needed to make the initial discovery. The different capabilities of university researchers as compared with industrial R&D teams are an obvious example."); Jackson, *supra* note 9, at 15 (observing that expertise needed for gene isolation and subsequent applications involving the gene fragment are drastically different.)

[245] *See* Scherer, *supra* note 9, at 1362 ("[A] single entity is not likely to perceive and back financially all the various derivative development possibilities. FN61").

[246] A benefit of spreading competition is that it removes the incentive of parties to compete early in the innovation process, when the technology is least certain and most speculative to a more rational time later in the innovation cycle.

[247] See discussion surrounding supra note 189.

[248] See discussions surrounding supra notes 152 and 154. However, they key is to do so without disincentivizing subsequent innovators. As Scotchmer has noted, the key is to introduce "incentive mechanisms … to make sure that earlier innovators are compensated for their contributions, while ensuring that later innovators also have an incentive to invest." Scotchmer, supra note 4, at 127.

[249] See supra note 195.

[250] If the follow-on innovations are really that predictable, the pioneer would probably, simply on first mover advantages of having built up expertise in the area, be the party most likely to make and corner the patent rights of the envisioned follow-on innovations regardless of the original patent scope. Broad patents are not necessary for original pioneers to internalize follow-on benefits since in predictable environments they are expected to make the follow-on innovations anyways Non-patent incentives include head start, expertise retention, professional recognition, etc. *See, e.g.,* Scherer, *supra* note 9, at 1350.

[251] Some examples of duds from Popular Mechanics – 1928: predicting that 50-100 years into the future, "milk and butter will be derived from kerosene instead of cows"; 1932: agreeing with Churchill that "We shall escape the absurdity of growing a whole chicken in order to eat the breast or wing, by growing these parts separately under a suitable medium"; 1940: predicting that robots will end the need for humans to perform drudgery work; several times since 1940: predicting the existence of flying car in every American garage; 1941: predicting in less than 50 years nuclear powered car that will drive "5,000,000 miles without refueling"; 1950: predicting that people will all be living in mobile homes made of synthetic materials since natural resources such as "by 2000, wood, brick and stone [will become] too expensive" for such uses; 1954: predicting that by 2004 "Air transportation [will make] the multi-family apartment house obsolete, as each family now needs a private landing strip." See "Greatest Hits (And Misses) Of Popular Mechanics," available at http://www.popularmechanics.com/science/time_machine/1288761.html?page=3&c=y.

[252] Despite the similarities between pharmaceutical product and gene product patents, I do concede one significant difference. Pharmaceutical patents typically cover discrete innovations, which overlap little with subsequent innovations, while gene patents involve basic knowledge type innovations that subsequent innovations will depend. Pharmaceutical product patents are often justified on the ground that they are much easier to enforce than process and use patents. Despite the convenience, the use of pharmaceutical product patents as proxies for process and use patents can be justified in the end only because the downside of broad pharmaceutical patents is limited due to the discrete nature of typical pharmaceutical innovations (note the *Amgen* and *Scripps* examples show that this is not always the case). The same cannot be said of gene innovations. Almost all foreseeable future discoveries and applications in biotechnology will rely in some way on the use of a set of (limited) genes sequenced today. Broad gene patents will drastically impede these future innovations. Unlike pharmaceutical patents, gene patents can not serve as an effective proxy for genetic innovations.

[253] As discussed earlier, each pharmaceutical innovation typically involves a combination of process innovation over the extraction or manufacturing processes and use innovation over the use of the a compound to deliver a specific therapeutic effect. See supra note 235, discussions surrounding 130-133.
[254] For the most part today, genes are sequenced and isolated from nature rather than created artificially. In the future, if scientists start modifying sequences or creating sequences *de novo* rather than just copying and transferring genes from one source to another, that might be another matter.
[255] Sequencing have become increasingly routine and need not be incentivized through patents. See supra notes 20 and 27.
[256] The discovery of a gene's sequence or function constitutes basic scientific knowledge or discovery of a natural phenomenon, which has traditionally been deemed nonpatentable and incentivized through extra-patent incentives such traditional science-based prestige and recognition. See discussions surrounding supra notes 49-50; supra notes 53 and 238.
[257] For example, the use of a gene or a set of genes (as in DNA micro arrays) to diagnose a disease could be patentable if the use of the gene or set of genes is not obvious given a disease's etymology (assuming that a disease's etymology, as subject matter of a basic science, is not patentable. See discussions surrounding supra notes 49-50; supra note 238.). Similarly, the use of a gene to produce a drug or the targeting of a gene to treat a disease could also be patentable if the use of the gene or set of genes is not obvious given basic scientific knowledge of the underlying biology.
[258] Jackson, note 9, at 17 (noting that "firms that hold the patents on genes involved in breast cancer and Alzheimer's disease have reportedly exercised their patent-given right to be the sole performer of tests for those defects"); id. (noting that "Physicians and academic medical centers have asserted that high fees and strict licensing terms are already making it difficult to do diagnostic genetic tests for patented genes.").