Rethinking Rights in Biospace

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ABSTRACT

Twenty-five years ago, Federal courts opened the door to the biotechnology revolution by granting patents on genetic inventions. The nature of such inventions, however, increasingly conflicts with the implications of rules created for mechanical products. In particular, across five disparate doctrines, courts are struggling with the question of whether the definition of a biotech invention should include things beyond the state of the art at the time of the invention. Reaching beyond the state of the art may make sense for mechanical inventions, but it is wreaking havoc in doctrines related to biotechnology.

A doorknob is a doorknob, regardless of whether it is made of wood or glass. A doorknob has no parts we can't identify, and there is no hint that the doorknob may be integrating with the door in ways we never dreamed of. Can we really say, however, that an antibody is an antibody, no matter how it works or what materials it is made out of?

This article argues that in uncertain arts such as biotechnology, the definition of an invention should be limited to the state of the art at the time of the invention. Granting rights beyond knowledge at the time of the invention projects an enormous shadow across the future and creates untenable results. The temptation to restrain that reach has led to strange doctrinal twists and an unworkable body of law. After twenty-five years of experience, it is time to rethink our view of the proper shape of rights in this realm.

INTRODUCTION

Twenty-five years ago, the Supreme Court opened the door to the biotechnology revolution by granting inventors the right to hold patents on genetically engineered organisms. In the seminal case of *Diamond v. Chakrabarty,* the Court ruled that inventors can patent an

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organism itself, not just the process of creating it.[1] Despite its revolutionary nature, the opinion was carefully crafted with familiar legal doctrines. The case and its progeny would treat biologic inventions, such as genetically engineered organisms and laboratory crafted genes, the way we treat mechanical products, such as dishwashers and doorknobs.

Thinking of biologic inventions as products helped pave the way for the explosion in the biotechnology industry. The nature of these inventions, however, increasingly is in conflict with rules that were crafted with simple mechanical products in mind. In particular, across five disparate doctrines, courts are struggling with the question of whether the definition of a biotech invention should include things beyond the state of the art at the time of the invention.

In patent law, we define a product by identifying its structure. Once the structure is identified, the inventor then controls the product, no matter what materials are used to make it, or what method is used to construct it. For example, suppose our simple mechanical invention is a doorknob. Once the patent holder identifies the "doorknob" invention by describing the structure of a doorknob, the patent holder controls all doorknobs. This is true regardless of whether the doorknobs are made of wood or glass or plastic. The rule is intended to protect inventors from those who would make minor alterations and claim "a new product."

While such a rule may make sense in the context of simple mechanical inventions, it is wreaking havoc in doctrines related to biotechnology. Suppose the invention is not a doorknob but an antibody. The inventor begins by isolating and identifying a harmful agent, perhaps something that causes cancer in humans. Next, the inventor isolates and identifies a single

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assistance.

[1] Diamond v. Chakrabarty, 447 U.S. 303 (1980) (interpreting Patent Code Section 101 which lists patentable subject matter).

antibody that binds with the harmful agent. Based on that work, the inventor claims the right to all antibodies that bind with the harmful agent.

In simplified terms, the inventor is claiming the class of things created by the immune system that bind with the relevant agent. Analogous to claiming the class of doorknobs, the inventor is claiming the class of relevant antibodies, no matter what materials are used to make the antibodies or how they are constructed.

We know much more about doorknobs, however, than we do about antibodies. For example, we know much more about the materials that can be used to construct doorknobs than we do about the materials that can be used to construct antibodies.

Suppose that at the time of the invention, antibodies were made in the lab using DNA-encoding materials from mice. At that time, no one in the field of science knew how to do much beyond that.[2] Suppose, however, that a later inventor constructed the relevant antibody using DNA encoding materials from a combination of different species, for example, one section from human materials and another section from mouse materials.[3] Or better yet, suppose an inventor was able to create an appropriate antibody using almost entirely materials from the human body, so that the antibody could be administered to human patients without the risk of rejection.[4] Suppose further that development of a humanized antibody that binds to a specific antigen would be quite difficult to accomplish, and humanized antibodies were entirely unknown when the mouse-based antibody was created. Should we, nevertheless, grant the inventor of the relevant mouse antibody control of all relevant humanized ones.?

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[2] *See* Hybritech v. Monoclonal Antibodies, 802 F.2d 1367, 1368 (Fed. Cir. 1986) (noting that ybridomas were originally produced by fusing mouse spleen cells with cancer cells).

[3] *See text accompanying notes x-y* (describing chimeric antibodies).

A doorknob is a doorknob, regardless of whether it is made of wood or glass. Can we really say, however, that an antibody is an antibody, no matter how it works or what materials it is made out of? Moreover, are we prepared to say that an antibody is an antibody at a time when there is much we do not know about why particular antibodies arise in the body and how they fit into the overall organic processes of the body?

This issue goes to the heart of the definition of an invention. Each invention must be defined in a way that appropriately captures the nature of the advancement as distinct from prior and future creations. One can think of this as the footprint of the invention. In other words, how far can an inventor reach against inventions that existed before and how far can an inventor reach against those that will come after. Modern case law is in a quandary over whether the footprint of an invention includes things unknown at the time of the invention.

The question of whether the definition of an invention includes things unknown at the time of the invention is creating chaos in the doctrines related to biotechnology. Despite precedent from cases related to mechanical inventions, courts increasingly shy away from permitting inventors to reach embodiments and characteristics unknown at the time of the invention. They have done so, however, without a comprehensive vision of either the problem of how to solve it. The result is a wealth of contradictory opinions and unworkable doctrines.

For example, cases concerning how far a biotech inventor can reach towards future inventions stand in contradiction to each other. Some opinions conclude broadly that the definition of an invention includes all embodiments, even those that could not have existed at the time of the invention. Other opinions use claim construction doctrines to limit a patent holder's

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[4] *See* Chiron v. Genentech, 363 F. 3d 1247 ,1252 (Fed. Cir. 2004) (holder of patent for mouse-based antibody that binds to a particular breast cancer agent sues Genentech for making humanized breast cancer antibody).

reach only to embodiments known at the time of the invention. Still others use a different set of doctrines to conclude that a patent holder's reach *sometimes* can include things that were unknown at the time of the invention, but not always. These contradictory doctrines, pulling in different directions, make it difficult to predict how far an inventor can reach towards later inventions.

Similar confusion exists in the doctrines related to how far an inventor can reach towards earlier inventions. In general, a new invention cannot be defined to include someone else's prior invention.[5] Some opinions, however, have found that prior art includes things that were inherent in a prior invention, but no one knew about. Other courts have declined to read prior art in that manner. Still other courts have answered the question of how far an inventor can reach towards prior inventions by reference to doctrines concerning how far an inventor can reach towards later inventions. As described above, doctrines related to defining earlier inventions are even more confused about whether an invention includes things unknown at the time of the invention. The convergence of these areas, however, demonstrates the futility of addressing piecemeal the question of whether the definition of an invention includes things unknown at the time of the invention.

One could argue that we should live with the inconsistencies. In fact, some scholars suggest that we define an invention one way for one set of doctrines and another way for another set of doctrines.[6] Such an approach, however, inevitably leads to the type of chaos we are now experiencing. How can we hold up a sphere and say, "when we look at it from one direction it is an apple, and when we look at it from another direction it is an orange"?

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[5] *See, e.g.,* Graham v. John Deere Co., 381 U.S. 1 (1966) (noting that Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available).

[6] *See* text accompanying notes x-y, *infra*.

We must establish a clear and comprehensive vision of how to define an invention. Without this, we cannot hope to create a workable body of law.

This article argues that in uncertain arts such as biotechnology, the definition of an invention should be limited to the state of the art at the time of the invention. Biospace inventions aren't like mechanical products. Rather, they are elements in a complex biological interaction, one which we understand only glimpses of at best. [7] In light of this, we cannot simply define their structure and then grant rights to all embodiments of that structure and everything inherent therein.

Granting rights beyond the state of knowledge at the time of the invention can project an enormous shadow of rights across the future and lead to untenable results. The temptation to restrain that reach is leading to strange doctrinal twists and an unworkable body of law. After twenty-five years of experience, it is time to rethink our view of the proper shape of rights in this realm.

I. THE STATE OF KNOWLEDGE IN BIOSPACE INVENTIONS

A. Patenting Living Organisms

In 1972, a microbiologist named Ananda Chakrabarty filed a patent application for a genetically engineered bacterium capable of breaking down multiple components of crude oil.[8] Although natural bacteria found in nature could degrade individual components of oil, no natural

[7] For example, Anne Magurran has noted that genes do not act singly, but in complex networks intermeshing biochemical pathways that form a tangled web of development. *See* Anne E. Magurran, *Its Not All in the Genes,* New York Times, Book Review (August 29, 2004) (citing Henry Gee's discussion of the German school of naturphilosophie and its relevance for modern genetic theories).

bacteria could degrade a combination of oil components. This made Chakrabarty's invention particularly promising for cleaning up oil spills.[9]

Chakrabarty's application included claims related to the *process* for manufacturing the organism, claims which were approved without much consternation.[10] The more difficult claims concerned rights to the living organism itself.

The patent examiner rejected Chakrabarty's claims related to the organism itself on grounds including that living things are not patentable subject matter because they are nature's creation rather than man's. The case was eventually appealed to the Supreme Court on the question of whether living things may be patentable subject matter.[11]

Patentable subject matter is governed by Section 101 of the Patent Act. The section states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent. . . ."[12] The Supreme Court concluded that Congress intended to provide a wide scope for patentable subject matter, one that would include the types of laboratory-created matter claimed by Chakrabarty.[13] "Congress thus realized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent's microorganism is the result of human ingenuity and research."[14]

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[8] *See* Diamond v. Chakrabarty, 447 U.S. at 305-306.
[9] *See id;* John M. Conley & Robert Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part II)*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 371, 371-72 [hereinafter Conley & Makowski Part II].
[10] *See* Diamond v. Chakrabarty, 447 U.S. at 305-306.
[11] *See id.*
[12] 35 U.S.C. § 101.
[13] *See id.* at 308 (describing expansiveness of the terms); *id.* at 306 (describing the inventions as laboratory-created micro-organisms).
[14] *See id.* at 313.

After Chakrabarty, it was clear that laboratory- created inventions with characteristics markedly different from nature are patentable subject matter, assuming of course that that the inventor could identify the potential for a significant utility.[15] The decision announced clearly that inventors could protect the organism itself, not just the process of creating it.

To create his invention, Chakrabarty used a process that can be classified as genetic engineering but did not involve recombinant DNA.[16] Many modern biologic inventions are composed of recombinant materials. Others are created as a result of techniques that involve recombinant materials or bioengineering. To avoid the technicalities of what constitutes biotechnology or one type of biologic invention verses another, I have chosen the term biospace. One can think of biospace as the commercial space that includes things such as biotech creations and inventions produced as a result of techniques that involve bioengineering or biotechnology.

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[15] *See id*. at 310. Some commentators have argued that the biotech revolution would have moved forward unimpeded without Chakrabarty. Inventors would have relied on patents for the process of creating the thing, rather than also obtaining a patent on the thing itself, or would have protected the invention as a trade secret. *See* YOUNT, *supra* note x, at 66 (citing patent attorney Mitchel Zoler that the decision was "trivial law" and patent attorney Donald Dunner that the ruling was not life or death for the industry). Others have argued that the decision broke no new legal ground but provided only a minor clarification of existing law. Nevertheless, the decision provided a tremendous boost to the biotech industry. *See id.* Following the ruling, the Patent and Trademark Office felt free to rule on the dozens of applications pending on genetically engineered organisms. In addition, publicity from the decision stimulated investment in the industry. *See id.;* Richard A. Epstein, Steady the Course: Property Rights in Genetic Material 44 (Working Paper No 152 (2d Series), Olin Program in Law and Economics, University of Chicago Law School), online at http:// www.law.uchicago.edu/Lawecon/index.html (noting that Chakrabarty helped spur the huge biotech boom).

[16] *See* LISA YOUNT, BIOTECHNOLOGY AND GENETIC ENGINEERING 62 (2000). Some legal scholars do describe Chakrabarty's invention as a recombinant process, but Yount explains that Chakrabarty's invention should not be considered recombinant because the individual plasmids were unaltered. *Compare* Conley & Makowski Part II *with* YOUNT, *supra*. For a description of recombinant DNA, see *infra* text accompanying notes x-y.

B. From Patenting Whole Organisms to Patenting the Components of Life

Chakrabarty concerned rights to living bacteria. In 1987, the Patent and Trademark office extended the doctrine to include rights to more complex organisms such as oysters, although the PTO carefully excluded humans. With resolution of the question of whether patentable subject matter could include a whole living organism, the 1987 ruling extended the notion to include components of life, such as human genes, cells, and organs.

To protect various components of life, the courts and the PTO have relied on a combination of two types of authorities. The logic begins with the notion from Chakrabarty that patentable subject matter includes things found in nature as long as the inventor has changed the product such that it differs from the naturally occurring form.[17] In the case of components such as human genes, authorities hold that the invention differs from the naturally occurring form when the gene has been isolated and purified from its natural setting.[18]

The general rule that patents may be granted on things purified and isolated from their natural state can be traced to a decision by Judge Learned Hand in 1911.[19] In Parke-Davis v. Mulford, Judge Hand granted a patent on a substance purified from the adrenal glands of cadavers. The opinion reasoned that although the relevant substance already existed in nature, the purified form could constitute a new product because the purified form allowed a new and practical use. [20]

The logical basis for patenting many biospace inventions rests on both the Chakrabarty and the Parke-Davis lines of cases. In many recombinant technologies, for example, genes are

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[17] *See* Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001) at 1093. (citing Chakrabarty as a basis for patenting genes); Gulliford at 722.
[18] *See* PTO 2001 Utility Guidelines at 1093.
[19] *See* Parke-Davis Co. v. H. K. Mulford Co. 189 F. 95 103 (C.C.S.D.N.Y. 1911), *aff'd* 196 F. 496 (2d. Cir. 1912); *see also* Merck & Co. v. Olin Mathieson Chemical Corp., 253 F.2d 156 (4th Cir. 1958).
[20] *See* Parke-Davis & Co. v. Mulford Co., 189 F. 95, 103 (1911).

isolated from their natural state, similar to the adrenaline in Parke-Davis, and then altered to behave differently, similar to the combined bacteria in Chakrabarty.

C. The One Embodiment Doctrine

Custom and practice in the courts and the patent industry have separated patentable subject matter broadly into two types of patents – products and processes.[21] The Patent Act itself does not employ such a neat, bipolar categorization. Rather, the Act lists the categories of patentable subject matter as processes, machines, manufactures, compositions of matter, and improvements thereof.[22] Nevertheless, the two general categories, and the distinction between them, have profound implications for patent rights.

Traditionally, a product claim is defined in terms of structural characteristics.[23] In other words, an inventor will claim rights to a particular machine, which can be described by its structural design. To qualify as patentable subject matter, however, the inventor must demonstrate that the product has a use beyond mere academic curiosity.[24] Once the inventor identifies a single use for the product, the inventor may exclude others from the full spectrum of the product,

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[21] *See, e.g.* Caterpillar, Inc. v. Detroit Diesel Corp., 961 F. Supp. 1249, 1252 (N.D. Ind. 1996), *aff'd,* 194 F.3d 1336 (Fed. Cir. 1999) (unpublished); Nestle-Le Mur Co. v. Eugene, Ltd. 55 F.2d 854, 858 (6th Cir. 1932) (machines, manufactures, and compositions of matter are all products or articles and differ fundamentally in nature from processes); 1 DONALD S. CHISUM, CHISUM ON PATENTS §1.02 (2003) (separating patentable subject matter into products and processes and noting that an applicant for a product patent is not required to specify whether it is for a machine, manufacture, or composition of matter). Varying phrases may be used to refer to these categories. *See, e.g.* Bandag, Inc. v. Al Bolser's Tire Stores, Inc., 750 F.2d 922, 923 (Fed. Cir. 1984) (using the terms "apparatus" and "method"); John R. Thomas, *Of Text, Technique, and the Tangible: Drafting Patent Claims Around Patent Rules*, 17 J. MARSHALL J. COMPUTER & INFO. L. 219, 225 (1998) (using the terms "artifact" and "process or method").

[22] *See* 35 U.S.C. § 101.

[23] *See* 3 CHISUM, *supra* note x, at § 8.05.

[24] *See* 35 U.S.C. § 101 (patentable subject matter described as "new and useful" inventions).

including any use of the product and any embodiment of the product, no matter how the embodiment is made.[25] In short, one embodiment gets you all rights.

The same is not true for a process claim.[26] If Chakrabarty had received a patent on the process of making his micro-organism, for example, he would have controlled only micro-organisms made through his process, not those made in any way. After the opinion in Chakrabarty, however, it was clear that biologic inventions could be treated as products with the full panoply of rights, not just rights on the process of creating the invention. With product rights

[25] *See, e.g.* Schering Corp. v. Gilbert, 153 F.2d. 428 (2d Cir. 1946); Maurer v. Dickerson, 113 F. 870, 874 (finding that the claim is not restricted to the product made by the described process but covers the chemical individual however produced); Utility Examination Guidelines, *supra* note x, at 1095 (noting that a patent on a composition gives exclusive rights to the composition for a limited time, even if the inventor disclosed only a single use); Symposium, *The Human Genome Project, Dna Science and the Law: the American Legal System's Response to Breakthroughs in Genetic Science*, 51 Am. U. L. Rev. 371, 392 (2002) (noting that the law extends patent rights to unknown embodiments with unknown utilities when the inventor has disclosed one embodiment with one utility); Ellen P. Winner, *Enablement in Rapidly Developing Arts – Biotechnology,* 1988 J. PATENT & TRADEMARK OFF. SOC'Y 608, 611 (Sept. 1988) (noting that a claim to a composition of matter is not limited to the method of making or using taught by the inventor); *see also* Continuous Curve Contact Lenses, Inc. v. National Patent Development Corp., 214 U.S.P.Q. 86, 117 (C.D. Ca. 1982) (noting it is well established that product claims without process limitations cover the product no matter how it is produced); *see also* Amgen, Inc. v. Chugai Pharmaceuticals, Co. Ltd., 927 F.2d 1200, 1213 (Fed. Cir. 1991) (noting that it is not necessary that a patent application test al embodiments of an invention); In Re Angstadt, 537 F.2d 498, 502 (CCPA 1976) (same). *But see* 3 CHISUM, *supra* note x, at § 9.05 n.1 (1987) (noting early cases with contrary results).

New uses may qualify for their own patents, in which case the parties hold patents that block each other. *See* Utility Examination Guidelines, *supra* note x, at 1095. The use patents, however, would be limited to that particular use or process and would not cover the full spectrum of uses of the product. One who wished to engage in the new use would need permission from both the inventor holding the original product patent and the inventor holding the new use patent.

[26] *See* O'Reilly v. Morse, 56 U.S. 62 (1854); Winner, *supra* note x, at 611 (noting that unlike composition of matter claims, an inventor of one method of achieving a result cannot claim all methods of achieving that result.

came the notion that one embodiment gets you all.[27] Process patent rights may be available for processes along the way, but the core right remains the right to the biospace product itself.

The one embodiment notion has different implications in the context of mechanical inventions than in the context of biospace inventions. With a machine, it is possible to define the invention by identifying the structure. This is not to suggest that the inquiry is always easy or clear cut, but at least the terms of the inquiry are more easily defined by focusing on the structure of the invention.[28]

Thinking back to the doorknob, for example, the structural design is what matters. It is what allows the thing to fit in the palm of your hand, rotate easily, and integrate with and latch the door. Varying the materials you make it out of or the type of screwdriver you use to make it is unlikely to make much difference in terms of what the invention has contributed to society. Furthermore, we know the elements that make up the doorknob, such as the grip, the shaft that goes into the door, and the latch that goes into the door frame. There are no pieces we can't explain or hints that the doorknob might be integrating with the door in ways we never dreamed of.

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[27] *See* Utility Examination Guidelines, *supra* note x, at 1095 (noting that DNA claims should be given the same claim scope as other composition of matter claims such that one use brings rights to all uses, even those unknown at the time of the patent).

[28] The machine analogy works reasonably well with chemical inventions. With chemicals, the invention generally resides in the structural design of the new compound. *See* COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN A KNOWLEDGE-BASED ECONOMY, NATIONAL ACADEMY OF SCIENCES, A PATENT SYSTEM FOR THE 21ST CENTURY, 76 (2004), *available at* http://www.nap.edu/books/0309089107/html/ [hereinafter A PATENT SYSTEM FOR THE 21ST CENTURY]. Although there are exceptions, normally, the method of making the compound is obvious once the structural design is determined, and the question of whether the compound is sufficiently inventive over prior compounds rests frequently on a comparison of the structural similarity. *See* Utility Examination Guidelines, *supra* note x, at 1095 (noting that DNA claims should be given the same claim scope as other composition of matter claims such that one use brings rights to all uses, even those unknown at the time of the patent); *See* Arti K. Rai,

With biospace inventions, however, we grant rights in the face of significant unknowns. While mechanical inventions are considered a predictable art, biospace inventions are considered an unpredictable art.[29] For example, consider patent rights to genes captured or manipulated in ways distinguishable from genes undisturbed in the human body. Genes are segments of the DNA double helix that exists inside cells from a living creature. Genes are made up of nucleotide building blocks.[30] These building blocks not only form the structure of the gene, they also serve as blueprints, providing the information necessary for the cell to conduct activities such as reproducing itself and constructing proteins.[31]

Although the sequence of the nucleotide building blocks forms the structure of the gene, there is nothing new about this structure. It already exists in nature and is not a new design of human ingenuity.[32] The problem for human ingenuity lies in identifying which sequences might be useful, achieving the technical hurdle of separating the sequence out from its natural form and recombining it in a more useful form, and finally, determining what to do with what you have.[33]

In many genetic experiments that lead to patents, scientists begin by identifying and separating out the DNA sequence that caries the coding information needed. They might be trying

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Intellectual Property Rights in Biotechnology: Addressing New Technologies, 34 WAKE FOREST L. REV. 827, 835-36 (1999).

[29] *See* Jeffrie A. Kopczynski, Note, *A New Era for § 112? Exploring Recent Developments in the Written Description Requirement as Applied in Biotechnology Inventions*, 16 Harv. L.J. 229. *Id.* at 237 (explaining that predictable arts, like the mechanical field, are those in which modifications to a system will have recognized, predictable effects and unpredictable arts are those in which there is insufficient learning to explain the effect that changed variables will have within a system).

[30] *See* KARL DRLICA, UNDERSTANDING DNA AND GENE CLONING: A GUIDE FOR THE CURIOUS 4, figure 1-2 (3rd Ed. 1997).

[31] *See id.* at 2-3.

[32] *See* A PATENT SYSTEM FOR THE 21ST CENTURY, *supra* note x, at 76; *see also* Amgen v. Chugai, 927 F.2d 1200, 1206 (Fed. Cir.) (noting that the parties had not technically invented a particular protein given that it exists naturally in the human body).

[33] *See id.* (technical hurdle lies in determining the sequence).

to create large amounts of a particular protein, for example, that could be administered to human patients. Having identified and separated out the relevant sequence, they then prepare a piece of carrier DNA into which they can splice the relevant DNA sequence. This carrier DNA is called a vector. Finally, they cultivate hosts cells capable of incorporating the carrier DNA and prepared with the proper materials so that the cell's own mechanism uses the coding information from the relevant DNA to create the desired protein.

Out of this enterprise, scientists might claim rights to the following products: the isolated and purified DNA sequence, the carrier DNA that holds the sequence, and a transformed host cell that has incorporated the vector and produces the protein.[34] Scientists, hoping to publish their work in a respected journal would recognize that the publication could claim no more than the narrow task that had been accomplished. For example, the scientists could claim as their own work no more than the achievement of getting a particular carrier DNA to include the sequence in a particular type of cell. One could publish that and no more. The question for patent rights, however, is more expansive. Rights to the invention described above, for example, would have little value if a second comer could alter the vector slightly and escape the prior inventor's work and the reach of the patent. Thus, patent rights to this type of recombinant invention have been defined to include the isolated and purified sequence in any vector and in any host cell that includes the vector.[35] Once again, analogous to the class of doorknobs, we are granting rights to the class of pieces of carrier DNA with the sequence spliced in, for example, regardless of what materials the carrier DNA is made up of. We grant these rights, however, in the face of significant unknowns.

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[34] Rebecca S. Eisenberg, *Reaching Through the Genome*, *in* SCIENCE AND CENTS: PROCEEDINGS OF THE 2002 CONFERENCE ON EXPLORING THE ECONOMICS OF BIOTECHNOLOGY 105, 106 (John V. Duca & Mine K. Yücel, eds., 2002).

Consider, for example, the issue of noncoding regions of DNA. As described above, the nucleotide building blocks of genes serve as blueprints for constructing proteins or for starting and stopping the process of protein production. Vast sequences of these nucleotide building blocks, however, do not appear to serve any such purpose. Although these sequences exist in the DNA, they drop out as the DNA information is transferred through different forms on the way to the creation of proteins. Scientists have dubbed these stretches "noncoding" regions or "junk DNA." For a quarter of a century of genetic research, they were considered irrelevant or evolutionary junk.[36]

In the last few years, however, researchers have uncovered striking evidence that noncoding regions perform different but essential functions in the human biologic process.[37] For example, scientists have determined that changes in just 2 noncoding nucleotides determine whether a person is lactose intolerant after weaning.[38]

More importantly, many so-called "noncoding regions" code for RNA rather than proteins. Scientists are discovering that RNA performs essential functions either alone or in conjunction with proteins, making these noncoding regions essential to human function.[39]

These discoveries will have little effect on patent rights granted under many of the first generation of gene patents. Such patents described the sequences in the form of a later translation, after the noncoding regions have dropped out. Nevertheless, where patents have been granted for

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[35] *See* Eisenberg, *supra* note x, at 106 .
[36] *See* W. Wayt Gibbs, *The Unseen Genome: Gems Among the Junk*, Scientific American, Nov. 2003, at 48–49.
[37] *See, e,g, id.*; Misia Landau, *Junk DNA Yields New Kind of Gene: Regulates Neighboring Gene Simply by Being Switched On*, Focus: News From Harvard Medical, Dental & Public Health Schools (June 4, 2004); Sabine Schmitt & Renato Paro, *A Reason For Reading Nonsense*, Nature, Vol. 429 (June 3, 2004).
[38] *See* C. Claiborne Ray, *DNA Junk or Not?* New York Times (March 4, 2003) (describing the effects of changes in 2 introns).

something that encompasses the entire DNA sequence, including coding and noncoding regions, the inventor may now control far more than imagined at the time of the invention. Similarly, patents that grant control of a gene sequence and a vector or host cell that encompasses that gene in a form that allows it to continue to function may be granting control of many hidden substances and operations that we have yet to decipher.

Consider further the issue of patents related to antibodies. Antibodies defend us against infection by binding to viruses and toxins in our system and interacting with such harmful agents to inactivate them.[40] Antibodies are proteins produced by immune cells in response to instructions from the genes that are active in those cells.[41] Knowing which antibody binds to a particular disease agent as well as manufacturing and manipulating such antibodies can be important in treating diseases ranging from AIDS to cancer to the common cold.

Suppose that an inventor has isolated a particular disease-causing agent, and we know that antibodies will bind to that agent in the human system. Having isolated the harmful agent, the inventor can then claim rights in all antibodies that will bind with the harmful agent. This is true despite the fact that the inventor may not have isolated and identified any of those antibodies.[42]

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[39] *See* Gibbs, *supra* note x, at 49.

[40] *See* BRUCE ALBERTS ET AL, MOLECULAR BIOLOGY OF THE CELL 1375-76 (4th Ed.). Without antibodies, a foreign agent, also called an antigen, would bind to our cells interfering with or altering their activity. To prevent this, antibodies step in, bind to the foreign agent and interact with it, rendering it harmless.

[41] Each cell contains all of our genes, but only certain genes will be activated in each cell.

[42] For example, in Noelle v. Lederman, the Federal Circuit commented that "based on our past precedent, as long as an applicant has disclosed a 'fully characterized antigen,' either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen." *See* Noelle v. Lederman, 355 F.3d 1343, 1349 (Fed. Cir. 2004) (denying patent because applicant not only failed to describe the antibody but also failed to describe the antigen to which it binds). Similarly, Patent and Trademark Office Guidelines on written description include an example stating that" if it is well known that antibodies may be made against any protein, then the

The logic of granting these rights rests on the amount of information we already know about antibodies combined with the information gained once we have the harmful agent. We know much about the structure of antibodies. For example, a typical antibody has a y-shaped structure made up of 4 chains of amino acids, two identical heavy chains, and two identical light chains.[43]

Ordinarily, we would not allow an applicant to claim something by its function.[44] Thus, in the antibodies example, we would not ordinarily allow a claim to a group of things identified by the function of their propensity to bind with a particular agent, but rather we would require structural identification.[45] The Patent and Trademark Office will allow this claim, however, on the basis of the functional information combined with the structural information that we already have about antibodies in general.[46]

The problem with granting rights in this area lies with the amount of information we don't have. Although the general structural features of antibodies were realized nearly four decades ago, it is the slight differences between antibodies that account for their ability to discriminate between targets. The rules governing the development of these slight differences remain elusive.

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inventor may claim any antibody that binds to antigen X without specifically disclosing such antibody." *See* PTO Synopsis of Application of Written Description Guidelines, at 59-60.

[43] *See* ALBERTS ET AL., *supra* note x, at 1376.

[44] An exception to this rule is a means plus function claim.

[45] *See, e.g.,* Eli Lilly & Co. v. American Cyanamid Co., 82 F.3d 1568, 1568 (Fed. Cir. 1996) (noting that when a gene material has been defined only by a statement of function or result, such statement alone does not adequately describe an invention).

[46] Jennifer L. Davis, *The Test of Primary Cloning: A New Approach to the Written Description Requirement in Biotechnological Inventions,* 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 469, 478 (2004); s*ee also* Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, para. 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1104 (Jan. 5, 2001); Enzo Biochem, Inc. v. Gen-Probe, Inc., 296 F.3d 1316, 1324-25 (Fed. Cir. 2002).

More importantly, different antibodies bind to different places on the harmful agent and disarm the harmful agent in different ways. In addition, some antibodies may be more useful than others. For example, some antibodies may bind with the harmful agent but fail to turn off its damaging activity. Claims to the class of antibodies generally are not limited to those that bind to the same place or perform in the same way.

Antibodies also may have cross-reactivity with harmful agents other than the one identified in the invention. Suppose that based on isolating and identifying a harmful agent, an inventor claims all antibodies that bind with that agent. Later, it turns out that one of these antibodies also binds with something else or performs some other function unrelated to the harmful agent. The inventor still holds rights to that antibody for any operation and in any context.

The notion that later research may yield new information about biological elements and processes is not merely theoretical. Consider the case of Schering v. Amgen.[47] The case concerned patent rights related to a particular leukocyte interferon. Leukocytes are white blood cells and interferons are proteins that play important roles in fighting viruses and tumors.[48] When the patent application was filed, scientists viewed leukocyte interferons as a single category.[49] While the application was pending, scientists determined that different species of interferons exist.[50] This revelation lead to a change in the scientific terminology as well as questions for the Federal Circuit concerning how to treat the patent.[51]

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[47] Schering Corp. v. Amgen Inc., 222 F. 3d 1347 (Fed. Cir. 2000).
[48] *See id.* at 1349.
[49] *See id.* at 1352.
[50] *See id.*
[51] *See id.* For a more detailed discussion of *Schering v. Amgen*, see text accompanying notes x-y *infra.*

The examples above highlight different angles on the problem of granting rights in the face of significant unknowns. In some cases, we know there are things we don't know. In others, experience suggests science will show us things we have never dreamed we didn't know. Whether we are talking about known unknowns or unknown unknowns, the patent system is faced with the problem of granting rights in the face of incomplete information. This is particularly true of biospace inventions in which we may never fully solve the mystery of the human body and the intricate interactions of its myriad parts and functions.

Waiting for full illumination is unlikely to produce the types of incentives we would wish to encourage scientists to continue the hunt. Despite the extent of uncertainties and unknowns in biospace, inventors are creating significant advances in the science, ones that provide tangible benefits to society and substantially promote progress in the field.[52] Given the commercial realities for biospace companies, the challenge is to craft rights in a way that has some economic vitality and reflects the inventor's contribution without reaching into unknown territory and hindering downstream innovation.

II. DOCTRINAL CHAOS

Although the one embodiment notion may make sense for mechanical inventions, it leads to uncomfortable results for fields in which much is unknown at the time of the invention. [53] Struggling with the implications of the rule, courts have introduced a variety of doctrinal rules that

[52] *Cf.* Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological* Inventions, 13 Berkeley Tech. L.J. 615, 649–652 (1998) (criticizing the Eli Lilly decision on the grounds that the resulting doctrine does not reflect the realities of scientific contribution).

[53] For the purposes of this article, I refer to the time of the invention. One could further consider, however, whether the proper moment for measuring the time of the invention is the moment of creation or the moment of the patent application.

stand in contradiction to each other and point in different theoretical directions. In particular, these cases fail to establish a consistent vision of whether the definition of an invention includes anything beyond the state of the art at the time of the invention. The tension can be seen both in doctrines related to how far a patent holder can reach towards later inventions and how far a patent holder can reach towards prior inventions.

A. How Far Can a Patent Holder Reach Towards Later Inventions?

On the question of whether the definition of an invention reaches beyond the state of the art at the time of the invention, the contradictions are most striking in the doctrines related to how far a patent holder can reach towards later inventions. In that arena, some opinions conclude broadly that one embodiment grants rights to all embodiments, even those that could not have existed at the time of the invention. Other opinions use claim construction doctrines to limit a patent holder's reach only to embodiments that could have existed at the time of the invention. Still others use a different set of doctrines to conclude that a patent holder's reach sometimes can include things that beyond the state of the art at the time of the inventions and sometimes not..

For example, the *Amgen v. Hoechst* decision in 2002 held broadly that one embodiment of an invention brings rights to all embodiments of the invention, even those beyond the state of the art at the time of the invention. The *Hoechst* case concerned erythropoietin (EPO), a hormone that occurs naturally in the body and controls the formation of red blood cells, which transport oxygen from the lungs to other parts of the body.[54] Anemia, defined as an insufficient amount of red blood cells in the blood, can occur as a result of chronic kidney disease or heart disease, from

[54] *See* Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1319 (Fed. Cir. 2002).

the effects of chemotherapy to treat cancer, and from other causes. Increasing the EPO in a patient's system can help raise the level of red blood cells.

Early attempts to obtain EPO for treating anemic patients involved recovering EPO from surplus human blood or urine. The approach was complicated and yielded only small amounts of EPO that were very impure and highly unstable.[55]

Rather than purifying EPO from blood and urine, the patent holder in *Hoechst* used genetic engineering techniques to produce large amounts of the hormone.[56] The patent holder used information from the relevant protein, the hormone EPO, to predict and isolate the reverse transcript of the human DNA that is used to produce the protein.[57]

A reverse transcript is created when double stranded DNA opens like a zipper into two strands. An enzyme docks with one of the strands and slides along it, matching each nucleotide to its complement and creating a perfect complementary strand.[58] That complementary strand, also known as a reverse transcript, will be translated into amino acids that will twist and fold into the intricate three-dimensional shapes of proteins.[59]

Having created the reverse transcript, or RNA, the patent holder transferred it into a circular piece of carrier DNA. The carrier DNA was then transferred into Chinese hamster ovary cells which used their own transcription machinery to churn out large amounts of EPO.[60] The

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[55] *See id.* at 1321.
[56] *See id.*
[57] *See id.* at 1321-22.
[58] *See* W. Wayt Gibbs, *The Unseen Genome: Gems Among the Junk*, Scientific American, Nov. 2003, at 49.
[59] *See Amgen,* 314 F. 3d at 1321-22.
[60] *See id.*

patent holder received a patent covering a variety of claims including a claim to "non-naturally occurring" EPO.[61]

Rather than the traditional recombinant techniques used by the patent holder, the second inventor in *Hoechst* used a different approach to obtaining large amounts of EPO. The second inventor, in essence, figured out how to spike the start and stop mechanisms that control the production of EPO in human cells.[62] The inventor could then use human cells in the lab to produce large amounts of EPO that could be administered to patients.

The Federal Circuit in *Hoechst* ruled in favor of the patent holder, choosing the broad notion of one embodiment.[63] The court then applied this broad notion through the various challenges to the patent holder's ability to enforce its patent against the second inventor. In particular, the court held that the claims covered any EPO other than the way nature intended it, and were not limited to EPO produced from any particular source or by any particular method.[64] The court held further that for such product claims, the inventor need neither describe nor enable technological advances that arise after the patent application.[65] The court cited with approval the lower court's conclusion that "the specification's failure to disclose later-developed [ ] technology cannot invalidate the patent . . . the law makes clear that the specification need teach only one mode of making and using a claimed composition."[66] In short, the *Hoechst* court allowed the footprint of the invention to cover things beyond the state of the art at the time of the invention.

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[61] *See id.* at 1322, 1327-28
[62] *See id.* at 1325-26.
[63] *See id.* at [ ] (noting precedent is clear that claims are not perforce limited to the embodiments disclosed in the specification).
[64] *See id.* at 1329.
[65] *See id.* at 1331 (regarding written description) and 1335 (regarding enablement); *cf.* Utility Examination Guidelines, *supra* note x.
[66] *See Amgen,.* 314 F. 3d at 1335; *see also id.* at 1338-39 (reiterating that the lower court applied the proper logic to uphold the patent based on written description as well as enablement).

In contrast, other Federal Circuit decisions have used different doctrines to limit the forward reach of the patent. For example, the *Schering* case used claim construction to limit the footprint of the patent to things known at the time of the patent application.

The *Schering* case concerned proteins known as interferons that occur naturally in the body and play an important role in fighting viruses and tumors.[67] At the time of the invention, scientists knew of only 2 types of interferons, those produced by leukocytes and those produced by fibroblasts.[68] Leukocytes are white cells and fibroblasts are a common cell type found in connective tissue.[69] The patent holder filed claims related broadly to leukocyte interferons, that is, any interferon produced by white cells.[70]

Interferons, however, turned out to have many more subtypes than originally known, varying according to the strength of the activity they engage in, the type of activity they engage in, and the type of receptors they bind to.[71] Thus, the term "leukocyte interferon" covered many subtypes beyond the one that the patent holder had manipulated in his experiments. As information about the various subtypes came to light, a committee of scientists adopted new

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[67] *See* Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1349 (Fed. Cir. 2000). For example, in response to a viral infection, the body may secrete interferons that bind to receptors on non-infected neighboring cells inducing those cells to produce proteins that increase their resistance to the infection. *See* ALBERTS ET AL, *supra* note x, at 884.

[68] *See Schering*, 222 F. 3d at 1349.

[69] *See* ALBERTS ET AL, *supra* note x, at ___ .

[70] The patent holder successfully isolated the gene that codes for an interferon, creating recombinant molecules that contained the genes and could be transferred to host cells to continue producing the desired interferon. The patent claimed recombinant molecules that contain the gene and genetically engineered micro-organisms that contain such molecules.

[71] Shahla Al-Hasso, *Interferons: An Overview*, U.S. Pharmacist, *available at*http://www.uspharmacist.com/oldformat.asp?url=newlook/files/Feat/interferons.htm&pub_id=8&article_id=731 (last visited Jan. 14, 2005) [hereinafter *Interferons*].

terminology to describe interferons according to factors such as the type of cell that produces them, their binding affinity and certain physical properties.[72]

Following the nomenclature change, the inventor amended his patent application to remove the term "leukocyte interferons" and substitute interferons of the "IFN-α type". At the time of the amendment, however, even the term "IFN-α" included numerous subtypes of interferons that were different from the one that the inventor has successfully isolated and manipulated.[73]

The Federal Circuit panel in *Schering* expressed admiration for the patent holder's invention, describing the experiments as "elegant" and the work as "pioneering."[74] Nevertheless, the court limited the reach of the invention, confining it to the limits of scientific knowledge at the time of the patent application.[75]

To reach its limiting result, the Federal Circuit in *Schering* used doctrines related to claim construction. Traditionally, patent cases begin with an examination of the meaning of the terms in the patent. Words are parsed to try to devine their precise definition in the context of the patent. This determination, known as claim construction, proceeds as a matter of law. The relevant hearings are called "Markman hearings," after the 1996 Supreme Court case holding that claim interpretation does not reside within the purview of the jury.[76] Thus, claim construction issues are decided by the trial judge, and appellate courts review such issues de novo without deference to

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[72] *See Schering*, 222 F.3d at 1352; *Interferons, supra* note x.
[73] *See Schering*, 222 F. 3d at 1353.
[74] *See id.* at 1349.
[75] *See id.* at 1353 (finding that the term in the patent could not enlarge the scope of the patent to embrace technology arising after its filing).
[76] *See, e.g., id.* at 1351 (referring to the "pre-trial *Markman* hearing"). *See also* Markman v. Westwier Instruments, Inc., 517, U.S. 370, 378 (1996). For a detailed description of the widely varying district court procedural rules for Markman hearings, see JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 232-34 (2003).

the trial court's decision.[77] Once the patent claims have been construed, those accused of infringing the patent generally defend along two lines of argument -- that the claims are invalid or that the accused product does not infringe the claims as interpreted.

Claim construction was the sole issue on appeal in *Schering.,*[78] In the process of defining the claim terms, the court declared that claim terms are not permitted to embrace technology arising after the application.[79] The court found that "[t]he claim term as used in the [patent] did not and could not enlarge the scope of the patent to embrace technology arising after its filing."[80] With this simple declaration, the court limited the footprint of the invention to the state of the art at the time of the application. In essence, the court was limiting the reach of the invention, freezing it to include only scientific knowledge when the application was filed.

The *Schering* court did not directly address the theoretical question of how far the footprint of the patent should extend and why we might make that choice. Rather, the court accomplished the limitation indirectly in its application of the rules of claim construction. Having declared that claim terms cannot reach to things arising after the application, the court proceeded to save the claim by reading limitations into it, adopting an inspired interpretation.

Both the terms used in the original claim and in the amended claim appeared to include subtypes discovered after the time of the invention, which the court had suggested was problematic. Normally, words in a claim should be interpreted according to their ordinary

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[77] *See, e.g.,* Key Pharm v. Hercon Lab. Corp., 161 F.3d 709, 713 (Fed. Cir. 1998); *see also* Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc) (landmark case declaring de novo appellate review for claim construction).
[78] *See Schering,*222 F.3d at 1349 (noting that Schering appeals only the district court's claim construction).
[79] *See id.* at 1353.
[80] *See id.*

meaning in the art at the time.[81] A court may overlook the ordinary meaning of a term, however, if the patent applicant expressly designates a particular definition for the term.[82] In amending his patent, the *Schering* applicant stated that "[i]n this application, the interferon nomenclature announced in *Nature* . . . is used. E.g., leukocyte interferon is designated IFN-α."[83] The court read this sentence from the amendment as expressing a broad intent to limit the claim only to what was known at the time of the invention.[84]

This interpretation is somewhat strained. The declaration in the amendment stops far short of declaring a limitation on the ordinary meaning of terms. It is a substantial leap to say that the act of narrowing the size of a group is the same as expressly limiting the claim to what could have been known at the time of the invention. More importantly, in narrowing the group, the applicant still chose a group larger than what was known at the time of the invention.[85] Thus, it is difficult to understand how choosing a group that reaches beyond what was known at the time of the invention evidences an intent to limit the claim to what *was* known at the time of the invention.

Nevertheless, the court interpreted that sentence as expressly limiting the claims to the specific science and knowledge at the time of the invention. The court, therefore, found a way to declare that the terms did not mean what they said, and that the claim was limited only to subtypes that could have been known at the time of the invention. In the process, the court suggested something about the proper footprint of the patent. The opinion suggested that as scientists

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[81] *See, e.g.,* Bell Atlantic Network Services, Inc. v. Covad Comm. Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001); York Prod., Inc. v. Central Tractor Farm and Family Ctr., 99 F.3d 1568, 1572 (Fed. Cir. 1996)

[82] *See Schering,* 222 F. 3d at 1353.

[83] *See id.* at 1352.

[84] *See id.* at 1353 (finding that the patentee expressly limited the meaning of the term IFN-α to define only the leukocyte interferon Dr. Weissmann described in his original application).

discover and distinguish variations of the product, the footprint should be limited to the science at the time of the invention. This approach stands in contrast with the opinion delivered 3 years later in *Hoechst* which embraces the broad notion of one embodiment and allows the patent holder to reach embodiments and variations beyond the state of the art at the time of the invention.

In contrast to both *Schering* and *Hoechst*, the decision in *Chiron v. Genentech*[86] used a different set of doctrines to address a patent holder's ability to reach embodiments that could not have been known at the time of the invention. Applying these doctrines, *Chiron* suggested a definition of the footprint of the invention that is not consistent with either of the prior cases.

The *Chiron* case concerned claims to monoclonal antibodies used in the treatment and diagnosis of breast cancer.[87] As described above, antibodies are Y-shaped proteins that defend the human body against harmful agents, such as viruses and toxins, by binding with such agents and interfering with their activity. [88] We generally refer to such harmful agents as antigens.[89]

About 25% of breast cancer tumors express unusually high levels of a protein named Her2. This fact suggests that Her2 plays a role in sustaining the development of the cancerous cells.[90] By blocking the activity of the agent Her2, scientists hope to prevent the growth of the

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[85] At the time of the amendment, scientists already knew that IFN-α itself had subtypes beyond what had been known at the time of the invention Even the *Nature* article cited in the amendment mentions subtypes of IFN-α interferons. *See id.* at [ ]
[86] Chiron v. Genentech, 363 F .3d 1247 (Fed. Cir. 2004).
[87] *See id.* at 1250.
[88] *See* ALBERTS ET AL., *supra* note x, at 1375- 76; *see also* text accompanying notes x-y.
[89] *See* note x, *supra.*
[90] *See* ALBERTS ET AL., *supra* note x, at 1358.

cancerous cells that may depend on it.[91] In particular, breast cancer patients may benefit from doses of antibodies that bind to and interfere with Her2.[92]

The challenge for scientists is producing a sufficient supply of stable antibodies that the human body can accept. In addition, as described above, antibodies vary in terms of where they bind to an agent, the way in which they interact with the agent, and the effectiveness of that interaction.[93] Monoclonal antibodies, however, are populations of identical cells that are developed to secrete a single antibody.[94] Given that a single antibody is produced, the antibody will bind to a specific site on an antigen and interact with the antigen in a consistent manner.[95]

The science of producing antibodies advanced dramatically in 1975 with the development of hybridomas. Ordinarily, the immune system cells that produce antibodies have a limited life span in the lab. Thus, although a population of homogenous cells producing a single antibody could be developed, the cells would die out, making it difficult to produce large amounts of a single, consistent antibody. Hybridoma technology, which involves fusing the desired immune cells with tumor cells, gives the capacity to replicate indefinitely.[96]

Early antibody populations were produced from hybridomas using mouse cells. Such antibodies could not be administered long-term to humans, because the patient's immune would eventually attack the mouse antibodies, risking toxic shock or death.[97] In response, scientists have turned to antibodies created from DNA encoding materials combined from different species. In

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[91] *See id.*
[92] *See, e.g.,* Chiron v. Genentech, *supra* note x, at 1252 (describing Genentech's product Herceptin, which binds to a particular human breast cancer antigen inhibiting the growth of cancerous cells).
[93] *See* text accompanying notes x-y.
[94] *See* VOET ET AL., FUNDAMENTALS OF BIOCHEMISTRY 677 (2002).
[95] *See* ALBERTS ET AL., *supra* note x, at 476.
[96] *See id.* at 476.
[97] *See id.* at 1251.

other words, the arms of the Y antibody may be created by genetic coding regions from a mouse while the tail of the Y may be created by genetic coding regions from a human. So-called "chimeric" antibodies are created in this combined fashion.[98] "Humanized" antibodies are created predominantly from human genetic coding materials, although they may contain some nonhuman portions.[99]

The patent holder in the *Chiron* case produced monoclonal antibodies that bind to the human breast cancer antigen Her2.[100] The original application disclosed one antibody, prepared using a hybridoma developed from mice.[101] Later versions of the application disclosed additional monoclonal antibodies that also bind to Her2, again produced by other hybridomas developed from mice.[102] Some of the variations revealed in the later versions of the application had binding affinities for different locations on Her2.[103]

The patent claimed all monoclonal antibodies that bind to Her2. The patent defined "monoclonal antibody" in the application as not limited in regards to the source or manner in which it is made.[104] In other words, the product of the patent application was defined as all antibodies that bind to the Her2 target, no matter how the antibody is derived, as long as it is derived other than the way in which nature intended.[105]

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[98] *See id.* at 1250-51.
[99] *See id.* at 1250-51.
[100] *See* Chiron v. Genentech, 363 F. 3d at 1250.
[101] *See id.* at 1251.
[102] *See id.* at 1251-52.
[103] *See id.* at 1251-52.
[104] *See id.* at 1251-52.
[105] Although the case did not discuss this aspect of the claim, presumably the claim was intended to reach all antibodies that bind to Her2 regardless of their binding location or method of interaction with Her2.

The patent holder sued a company making a product called "Herceptin", a humanized antibody used in the long-term treatment of breast cancer.[106] Neither chimeric nor humanized antibodies existed in the science at the time of the original patent application.[107] Thus, in the *Chiron* case, the patent holder was attempting to extend the footprint of the patent to embodiments beyond the state of the art at the time of the patent application.

In analyzing the claim, the Federal Circuit in *Chiron* chose an entirely different path than either of the paths take before. The *Schering* court had limited a patent holder's reach to embodiments that could have existed at the time of the patent and used claim construction doctrines to accomplish that limitation. The *Hoechst* court had refused to limit a patent holder's reach, remaining faithful to the one embodiment notion. The *Chiron* court, in contrast to both, limited a patent holder's reach, but by the disclosure doctrines, not by claim construction.

As described above, patent cases begin with an inquiry into the meaning of the words in the claims. Once claim construction is completed, an accused infringer generally proceeds by claiming that the patent is invalid and that the accused product does not infringe. To establish validity, a patent holder traditionally must show proper subject matter, utility, novelty nonobviousness, and proper disclosure.[108] The *Chiron* court chose to limit the footprint of the patent using doctrines related to proper disclosure.

Disclosure is governed by § 112 of the Patent Act. This section provides that the patent shall contain "a written description of the invention . . . in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

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[106] *See id.* at 1252.
[107] *See id.* at 1251.
[108] *See generally* MUELLER, *supra* note x (describing each element).

connected, to make and use the same."[109] The disclosure requirement is the patent holder's payment in the bargain of granting a patent. The government confers patent rights for a limited time in anticipation that society later will get the full benefit of the knowledge of those inventions.[110] Disclosure guarantees that society receives the benefit of the patent holder's knowledge.

In addition, early cases suggested that the disclosure requirements of § 112 and its predecessors not only guaranteed society's proper reward but also served to put others on notice of the rights claimed.[111] More recent cases have expanded the role of § 112 from explanation and notice to determining whether the inventor was properly in possession of the invention claimed.[112] To accomplish this expansion, the Federal Circuit in the 1997 case of *Eli Lilly* identified within the § 112 disclosure language two separate requirements, one for enablement and one for written description.[113] Enablement would continue to ensure that the public has sufficient information to understand and practice the invention. In contrast, written description would ensure that patent applicants were in possession of what they wish to claim.[114]

The new written description test is couched in terms of performing an accurate accounting of what the inventor actually possessed and when.[115] A court cannot determine what an inventor possessed at a given time, however, in the absence of assumptions about how far a

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[109] 35 U.S.C. § 112,
[110] *See, e.g.,* Grant v. Raymond, 31 U.S. 218, 219 (1832) (noting that description ensures that after the privilege expires, the public gets the benefit for which the privilege was allowed).
[111] *See* Evans v. Eaton, 20 U.S. 356, 424 (1822).
[112] For a description of the evolving role of § 112, see Robin C. Feldman, *Written Description and Enablement: Too Weak to Bear the Weight* (manuscript).
[113] *See* Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, ___ (Fed. Cir. 2004). (Rader, J. dissenting from denial of en banc).
[114] *See id.* at ___ (Lourie, J. concurring in the denial of en banc and defending the current written description doctrine).
[115] *See, e.g.,* Chiron v. Genentech, 363 F.3d. at 1255.

particular invention can reach. The new written description jurisprudence, therefore, has become the battleground for indirect struggles over how far a patent holder can reach.[116] It is within this context that the *Chiron* court uses written description to reduce the footprint of the patent for biotech inventions.

In *Chiron*, the patent holder tried to reach embodiments of the invention that could not have been accomplished at the time of the patent application.[117] The appeal centered on whether the patent holder's original application satisfied § 112.[118] On this question, the court faced precedent from the cases of *In re Hogan* and *Plant Genetic Systems.*

In re Hogan was decided by the predecessor court to the Federal Circuit regarding an invention in the field of chemistry.[119] Although the original patent application in *Hogan* was filed in 1953, amendments and continuations reached across two decades, with the Patent and Trademark Office (PTO) finally rejecting the 1971 application.[120] Under the Patent Act, an applicant can amend its patent but may not add any new matter to the application.[121]

In its rejection, the PTO objected that later incarnations of the application included versions of the original chemical that could not have existed decades before when the original application was filed.[122] Thus, the PTO objected that the rights sought reached far beyond the invention as defined in the original disclosure of the patent..[123]

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[116] *See* Feldman, *supra* note x, at [ ].
[117] *See* Chiron v. Genentech, 363 F. 3d at 1251.
[118] *See id.* at 1252 (framing the case as an appeal from determinations concerning written description and enablement).
[119] *See In re* Hogan, 559 F. 2d 595 (CCPA 1977).
[120] *See In re* Hogan, 559 F. 2d at 597.
[121] *See* 35 U.S.C. § 132(a) (prohibition on adding new matter by amendment).
[122] *See id.* at 600.
[123] *See id.*

In reversing the PTO, the *Hogan* court held that a patent applicant need not enable later developed technology, arguing that such a limitation would place an intolerable burden on a patent holder's ability to claim broadly.[124] With this approach, the *Hogan* court embraced a broad view of the footprint of a patent, allowing the reach to extend to embodiments beyond the state of the art at the time of the invention.

Grappling with the *Hogan* language 25 years later, a Federal Circuit panel in the case of *Plant Genetic Systems*[125] suggested that *Hogan* itself could be limited.[126] "We do not read *Hogan* as allowing an inventor to claim what was specifically desired but difficult to obtain at the time the application was filed, unless the patent discloses how to make and use it."[127] Under the approach outlined in *Plant Genetic Systems*, patent holders do not have to enable embodiments completely unknown at the time of the patent but must enable embodiments that were desired but difficult to obtain at the time of the patent.[128]

This reading of *Hogan* attempts to reign in a broad footprint that would allow patent holders to reach forward to embodiments that could not have been known at the time of the invention. After all, by reading *Hogan* in this fashion, the court changed the law from allowing patent holders to reach all embodiments beyond the state of the art to reaching only some embodiments beyond the state of the art. The limitation, however, has a perverse effect. In designing a coherent vision of the footprint of the invention, one would expect to reduce a patent holder's reach as technology advances farther away from what was known at the time of the patent. The more the science advances, the more we would anticipate that new products are

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[124] *See id.* at 606.
[125] Plant Genetic Systems N.V. v. Dekalb Genetics Corp., 315 F. 3d 1335 (Fed. Cir. 2003).
[126] *See id.* at 1340.
[127] *Id.*
[128] *See id.*

substantially different from what the patent holder accomplished and should not be covered by the patent. Thus, we would expect to create the strongest limits on a patent holder's reach for embodiments that are the farthest from the state of the art at the time of the invention.

The *Plant Genetic Systems* limitation, however, has the opposite effect. A patent holder's reach is most clearly protected in the case of advancements that are beyond anyone's imagination at the time of the invention. The patent holder's reach is denied for technology that is closer to the art at the time. Thus, the patent holder has more control over things vastly beyond the state of the art and less control for things close to the state of the art. This is the opposite of the effect that one would logically impose because courts again are looking for stop-gap measures to limit a patent holder's reach, rather than developing a comprehensive view of what should be protected.

Plant Genetic Systems suggested that a patent holder's ability to reach beyond the state of the art at the time of the invention could be limited through the enablement doctrine. Two months later, the *Chiron* court followed *Plant Genetic Systems,* finding that patent holders are required to enable some, but not all, embodiments beyond the state of the art at the time of the invention.[129]

The *Chiron* court went further, however, in its application of the written description doctrine. In written description, the *Chiron* court ruled that the patent holder could not possibly have described what did not exist in the art at the time of the invention.[130] Thus, the *Chiron* court ruled that patent holders who try to reach to embodiments beyond the state of the art at the time of the invention will fail on written description grounds, even if they survive enablement. At the end of the day in *Chiron*, therefore, patent holders can *never* reach embodiments beyond the state of

[129] *See* Chiron v. Genentech, 363 F. 3d at 1257.
[130] *See* Chiron v. Genentech, 363 F. 3d at 1255 (finding that the patent holder could not have described antibodies beyond the state of the art at the time of the invention.

the art at the time of the invention. The case, however, adopts a number of strange twists to reach that result and stands in contradiction to other cases.

The author of the *Chiron* opinion, Judge Rader, has railed against the Federal Circuit's elevation of written description to the level of a separate test in §112 jurisprudence.[131] In fact, Judge Rader continued his strenuous objections a few months after *Chiron* in his dissent from the Federal Circuit's refusal to take a written description case en banc.[132] In particular, Judge Rader has argued that the Federal Circuit's current separation of written description and enablement leaves juries with the cumbersome task of deciding that "the patent's disclosure can enable a skilled artisan to make and practice the invention, but still not inform that same artisan that the inventor was in possession of the invention. Nevertheless, the separation of written description and enablement becomes a happy circumstance for Judge Rader in *Chiron*, providing the vehicle for blunting the impact of *Hogan*.

Regardless of the technical conflicts concerning how the written description doctrine operates or how its fits with the enablement doctrine, the more serious conflicts are theoretical. Across a broad range of doctrines, the courts have adopted entirely inconsistent visions of the proper footprint of the invention and how far an inventor can reach towards things that come after. The *Hoechst* court suggested broadly that a patent holder could reach to all embodiments, including those that could not have existed at the time of the invention. The *Schering* court suggested through claim construction that a patent holder could *not* reach to things that could not have existed at the time of the invention. The *Hogan* court suggested through enablement that a

[131] *See* Enzo Biochem, Inc. v. Gen Probe, Inc., 323 F.3d 971 976-87 (Fed. Cir. 2002) (Rader, J. dissenting to denial of en banc); Moba B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1323 (Fed. Cir. 2003).
[132] *See* Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F. 3d 916 (Fed. Cir. 2004). (Rader, J. dissenting to the denial of en banc).

patent holder *could* reach to unknown embodiments. The *Plant Genetic Systems* suggested through enablement that a patent holder could reach some, but not all embodiments that could not have existed at the time of the invention. And the *Chiron* court suggested through written description that a patent holder could not reach any embodiments that could not have been known at the time of the invention.

B. How Far Can A Patent Holder Reach Towards Earlier Creations?

The section above described how defining an invention to include things beyond the state of the art at the time of the invention has led to chaos in the doctrines concerning how far a patent holder can reach towards later inventions. The same expansive notion is wreaking havoc in the doctrines related to how far a patent holder can reach towards earlier creations, whether created by nature or by other inventors.

Ordinarily, a patent applicant's reach is constrained by prior art. Patents are granted only for new inventions, not for things that are already available in the science.[133] If an invention already exists, it is not novel.

The novelty question, that is, whether the invention already exists in the prior art, should not be confused with the question of what is beyond the state of the art at the time of the invention. The two can be distinguished in the following fashion. An invention, like a doorknob, teaches something new. The inventor may then claim various embodiments of that doorknob based on materials and techniques available in the art. This article asks whether you also should be able to claim embodiments of your invention using materials and techniques unavailable in the art. Regardless of whether you can claim embodiments unavailable in the art, however, what you can't

[133] *See* 35 U.S.C. § 102 (requiring novelty).

do is claim something that already existed without anything new from you. If something already existed without anything new from you, your invention would be deemed "not novel", but rather "anticipated by the prior art."[134]

The classic case for anticipation requires that a single prior source must contain all of the essential elements of the current invention.[135] In other words, to argue that a current invention is anticipated by prior art, one must point to a single piece of prior art and find all of the essential elements within the four corners of that prior art.

Courts have broadened the classic definition of anticipation by allowing references to what a person of ordinary skill in the art would understand. Thus, although a piece of prior art might not have described a particular element of the claimed invention, the prior art may still anticipate if a person of ordinary skill in the art would have understood that the prior art reference included the element.[136] Thus, if a person of skill in the art would have understood that the element was included in the prior art, the prior art anticipates.

Similarly, although the test for anticipation requires a single reference and should not combine prior references, a court may look at additional references to interpret what a person of ordinary skill in the art would understand.[137] Understandably, courts have experienced some

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[134] *See* 1 CHISUM, *supra* note x, at § 3.02[1].
[135] *See id.; see also* Apple Computer, Inc. v. Articulate Systems, Inc., 234 F.3d 14, 20 (Fed. Cir. 2000) (finding that anticipation requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention); ATD Corp. v. Lydall, Inc., 159 F.3d 354 (Fed. Cir. 1998) (noting that a patent is invalid for anticipation when the same device of method, with all of the elements or limitations in the claims, is described in a single prior art reference); C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1349 (noting that when the defense of lack of novelty is based on a printed publication that describes the same invention, anticipation requires that the publication describe all of the elements of the claims arranged as in the patented device).
[136] *See* Helfix, Ltd. V. Blok-Lok, Ltd. 208 F.3d 1339, 1347 (Fed. Cir. 200);
[137] *See* Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1328(Fed. Cir. 2001) (noting that recourse to extrinsic evidence is permissible to determine if a feature is necessarily present, even if not discussed).

difficulty in distinguishing between the use of extrinsic evidence to explain a piece of prior art, which is permissible, and combining two pieces of prior art, which is not.[138]

Some opinions broaden the anticipation standard even farther, finding that a prior art reference can anticipate if the necessary element is inherent in the prior invention, even if those of ordinary skill in the art could not have recognized the element.[139] This interpretation expands the definition of anticipation beyond what one skilled in the art would know to things that are entirely unknown but contained in the invention.

For example, the case of *Schering v. Geneva*[140] concerned a patented antihistamine that is the active ingredient in the popular allergy medicine, Claritin.[141] Unlike other antihistamines available at the time of the invention, the Claritin antihistamine does not cause drowsiness.[142]

Six years after receiving the patent on the Claritin antihistamine, the patent holder also received a patent on DCL, a metabolite of its antihistamine.[143] A metabolite is a compound formed in a patient's body. As a patient's body digests, or metabolizes, a medicine, the medicine is chemically converted into a new compound, known as a metabolite.[144]

Scholars have expressed concern over patent holders' attempts to refresh their patents by patenting updated versions, alternative delivery methods, or other variations of the original

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[138] *See* 1 CHISUM, *supra* note x, at § 3.02[1][d] n. 26 (citing discussion of this dilemma in the case of Fenton Golf Trust v. Cobra Golf, Inc., 48 USPQ2d 1198 (N.C. Ill. 1998)).
[139] *See, e.g.,* Schering Corp. v. Geneva Pharms., 339 F.3d 1373 (Fed. Cir. 2003); *In re* Cruciferous Sprout Litigation*,* 301 F.3d 1343 (Fed. Cir. 2002); Mehl/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362 (Fed. Cir. 1999); *see also* 1 CHISUM, *supra* note x, at § 3.03[2][c].
[140] 339 F.3d 1373 (Fed. Cir. 2003).
[141] *See id.* at 1375.
[142] *See id.*
[143] *See id.* 1375-76 (explaining that the '233 antihistamine patent issued in 1981 while the '716 metabolite patent issued in 1987).
[144] *See id.* at 1375.

product. This practice is referred to as "ever greening," and one could argue that patenting metabolites is a form of ever greening.

When the patent on the Claritin antihistamine expired, generic versions entered the market. The patent holder sued the generics on the grounds that although the antihistamine patent had expired, the generics infringed the metabolite patent, which still had 6 years to go.[145]

The decision focused on whether the metabolite patent was invalid because it was anticipated by prior art.[146] Given the sequence of events in the case, the relevant prior art was the original Claritin antihistamine.[147] The key question concerned whether an invention is anticipated by prior art if the element is present in the operation of the prior art, despite the fact that those skilled in the prior art would not have recognized it.[148]

The *Geneva* court found that anticipation by prior art does not require recognition.[149] In other words, a prior art reference can anticipate if all elements are contained in the prior art even if a person of ordinary skill in the art would not have been able to recognize the disputed element as part of the invention.[150] Thus, the antihistamine anticipated the metabolite because the metabolite compound was inherently formed during the operation of the antihistamine invention, even though those of ordinary skill in the art did not know of this at the time of the antihistamine patent.

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[145] *See* Schering Corp. v. Geneva Pharms., 339 F.3d at 1375-76 (describing the timing of the patents and identifying the patent at issue in the suit).
[146] *See id.* at 1376.
[147] *See id.*
[148] *See id.* at 1377.
[149] *See id.* at 1377 (finding that "at the outset, this court rejects the contention that inherent anticipation requires recognition in the prior art").
[150] *See id.* at 1377 (holding that "recognition by a person of ordinary skill in the art before the critical date of the '716 patent is not required to show anticipation by inherency").

Another Federal Circuit panel reached a similar conclusion in the case of *In re Cruciferous Sprout Litigation.*[151] *Cruciferous* concerned a patent for a method of lowering the risk of developing cancer by selecting for particular vegetable seeds that will grow plants containing high levels of substances thought to reduce the risk of developing cancer.[152] The substances, glucosinolates, encourage the body to produce certain enzymes that are part of the body's mechanism for detoxifying agents that have the potential to cause cancer.[153] The inventors recognized that the amount of the desired substances varies from one broccoli plant to another, for example.[154] The inventors suggested selecting among the seeds of particular plants to sort for those that will produce high levels of the desired substances and assembling these into a food product as a method of reducing cancer in humans and animals.[155] The patent claimed a new method for treating cancer, not a new method for growing or harvesting sprouts.[156]

The Federal Circuit panel found that the invention was anticipated by the prior art of harvesting this class of vegetables for human consumption in general.[157] The patent holder had tried to argue that even if the prior art included eating your vegetables, nothing in the art identified the particular vegetables with the desired substances or suggested assembling a food product from the seeds cultivated with particularly high quantities of the substance.[158]

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[151] In re Cruciferous Sprout Litigation, 301 F.3d 1343 (Fed. Cir. 2002).
[152] *See id.* at 1345.
[153] *See id.*
[154] *See id.*
[155] *See id.* 1345-46.
[156] *See id.* at 1345-46 (describing the patent claim) and 1350 (noting that the patent holder does not claim to have invented a new kind of sprout or a new way of growing or harvesting sprouts).
[157] *See id*. at 1351 (noting that the prior art teaches sprouting and harvesting the very same seeds that the patents recognize as producing vegetables rich in the desired substance).
[158] *See id.* at 1349.

The court, however, concluded that those things were inherent in the prior art.[159] A person eating vegetables would have eaten some vegetables with the high quantities of the desired substances. Thus, there was nothing new in directing people to do something that had been done before. "[The patent holder] cannot credibly maintain that no one has heretofore grown and eaten one of the many suitable [particular seeds] identified by the patents."[160]

In particular, the court ruled that prior art can anticipate even if those of ordinary skill in the art would not have recognized the inherent characteristics or functioning.[161] "Stated differently, a sprout's glucosinolate content and Phase 2 enzyme-inducing potential are inherent characteristics of the sprout. It matters not that those of ordinary skill heretofore may not have recognized these inherent characteristics of the sprouts."[162]

As described above, the classic test for finding that an invention is anticipated by the prior art requires that a single piece of art must contain all elements of the claimed invention, a requirement that has been eased by allowing courts to consider what a person skilled in the art would have understood as inherent in the invention. The *Geneva* and *Cruciferous* cases ease the requirement even further by finding that a prior art reference can anticipate if the necessary elements are inherent in the invention, even if one skilled in the art would not have recognized or appreciated those elements.

Not all Federal Circuit panels agree, however, that prior art can anticipate even if those skilled in the art would not have recognized the elements. Some Federal Circuit decisions have

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[159] *See id.* at 1349-50.
[160] *Id.* at 1351.
[161] *See id.* at 1350.
[162] *Id*. at 1350 (citation omitted).

held, to the contrary, that prior art can anticipate only if the element or characteristic would have been recognized by those skilled in the art. [163]

The notion that an invention encompasses things inherent but unknown is consistent with the one embodiment concept. In both concepts, the footprint of the invention is defined broadly to include things beyond the state of knowledge at the time of the invention. With the inherency cases, Federal Circuit opinions again struggle with the implications of applying such a wide footprint, with some cases ruling that prior art includes things unrecognized in the arts and others declining to do so.

Within the opinions that would allow inherency for unknown elements, one can see an instinct to limit what can be patented by expanding the notion of prior art. In *Cruciferous*, for example, the court denied patent coverage by finding that the invention existed inherently in common activities. In *Geneva*, the court denied patent coverage by finding that the invention existed inherently in the applicant's own prior inventions. This would suggest an effort limit the ability of inventors to lock up rights by granting a large footprint to what has come before.

The problem with this approach is that, in the end, it expands what can be patented rather than limiting it. If the definition of a piece of prior art includes unknown elements, then the inventor holding the patent on that piece of prior art should be able to define the invention to reach

[163] *See,* ATD Corp. v. Lydall, Inc. 159, F.3d 534, 545 (Fed. Cir. 1998) (finding that to anticipate, a prior art reference must describe with sufficient clarity to establish that the subject matter was recognized by persons of ordinary skill in the art); Glaxo Inc. V. Novopharm Ltd., 52 F.3d 1043, 1047 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 988 (1995) (noting that a disclosure may anticipate by inherency where it would be appreciated by one of ordinary skill in the art); Continental Can CO. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269 (Fed. Cir. 1991); *see also* 1 CHISUM, *supra* note x, at § 3.03[2][c] (noting that Federal Circuit opinions have oscillated on the question of whether a person of ordinary skill in the art must recognize the existence of an inherent feature of prior art); *cf.* In Re Seaborg, 328 F.2d 996, 998-99 (CCPA 1964) (finding lack of anticipation on the grounds that the claimed product, if it was produced in the prior art process, was produced in such miniscule amounts and under such conditions that its presence was undetectable).

those unknown elements as well. After all, an invention is what an invention is. Why would we define an invention one way for one set of doctrines and another way for another set of doctrines?

Altering the inherency doctrine so that prior inventions are defined to include elements beyond what those in the art could recognize creates an expansive reach for all patent holders. Thus, an effort to reign in patenting in some cases has the perverse effect of expanding the footprint of patents in general.

In short, the inherency doctrine suggests defining an invention to include things beyond the knowledge of the inventor or the state of the art at the time of the invention. Although this arises in the context of how far an inventor can reach towards prior inventions, logically it should also apply in the context of how far an inventor can reach towards later inventions. In fact, a recent Federal Circuit opinion has already made this logical connection. The opinion takes inherency questions, in other words, those related to how far an inventor car reach towards earlier inventions, and links them to the doctrines concerning how far an inventor can reach towards later inventions. Thus, the opinion confirms the inextricable link between defining an invention for the purposes of delineating prior art and defining an invention for the purposes of delineating future art.

Specifically, in the case of *Elan Pharmaceuticals v. Mayo,*[164] a Federal Circuit panel found that when anticipation is based on inherency, the information must have been known in the art.[165] This opinion, therefore, followed the line of cases denying inherency for unknown elements, in contrast to cases such as *Cruciferous*[166] and *Geneva.*[167] Following publication of the

[164] Elan Pharmaceuticals, Inc. v. Mayo Found. for Med. Ed. & Research, 304 F.3d 1221 (Fed. Cir. 2002).
[165] *See id.* at 1228.
[166] *In re* Cuciferous Sprout Litigation, 301 F.3d 1343 (Fed. Cir. 2002)
[167] Schering Corp. v. Geneva Pharmaceutical, 339 F.3d 1373 (Fed. Cir. 2003)

opinion, the full Federal Circuit initially agreed to rehear the case en banc. The court withdrew the en banc order, however, when the panel reissued the opinion avoiding the question of whether inherency must be recognizable.[168]

The original panel opinion had upheld the patent at issue in the case. The opinion had adopted a narrow view of prior art by finding that prior art cannot anticipate unless the elements are recognized.[169] The reissued opinion similarly upheld the patent but avoided all discussion of inherency. Rather, in the reissued opinion, the court found that prior art does not anticipate if the prior art is not enabled.[170]

Although the final *Elan* opinion pursued a perfectly logical connection, the opinion makes the circle of confusion in this area complete. First, the results in *Elan* conflict with the cases finding that anticipation does not require recognition. Under those cases, prior art with unrecognized qualities does anticipate, while under *Elan*, prior art with unrecognized qualities, in the end, does not anticipate. The Federal Circuit cannot solve the conflicts in the inherency doctrine by deflecting questions into another doctrine. The results are still in conflict, in terms of whether the footprint of the invention can reach back to cover prior unrecognized elements.

Second, current conflicts within the enablement doctrine itself will lead to further confusion on the question of whether an inventor can reach back towards unrecognized

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[168] Elan Pharmaceuticals, Inc. v. Mayo Found. for Med. Ed. & Research, 314 F.3d 1299 (Fed. Cir. 2002) (en banc); Elan Pharmaceuticals, Inc. v. Mayo Found. for Med. Ed. & Research, 346 F.3d 1051 (Fed. Cir. 2003) (replacement opinion).

[169] *See Elan*, 304 F.3d at 1228.

[170] *See Elan, 346 F.3d at*1054. This holding fits logically with enablement's traditional role of ensuring that an inventor adequately teaches those of skill in the art how to practice the invention. If a patent reference, for example, serves to bring something into the prior art such that future inventors cannot claim it, then that reference must actually teach those of skill in the art how to do the invention. *See id.* at 1057.

elements.[171] As described above, the enablement doctrine is itself in disarray in terms of whether an inventor can reach things that could not have been known at the time of the invention. *Hoechst* and *Hogan* hold that an inventor need not enable information that could not have been known at the time of the invention while *Chiron* and *Plant Genetic Systems* hold that an inventor must enable some but not all of such information. [172] Tossing the inherency question into that realm places it at the center of opinions that point in different directions and guarantees further confusion.

Finally, if a prior art reference must satisfy the enablement doctrine in order to anticipate, then it must also satisfy written description. If a prior art reference must be described to anticipate, then the conflicts throughout both sets of doctrines will be complete. The same question of whether an inventor can reach back to unrecognized elements would be decided in a variety of ways depending upon which doctrinal box the court uses to frame the question and which line of cases the court follows. If decided based on inherency, some cases would find that the prior art anticipated even though there was no recognition in the art and some would find the opposite.[173] If decided based on enablement, some cases would suggest that the prior art may anticipate despite lack of knowledge by those skilled in the art,[174] and others would disagree with this proposition.[175] Still others would suggest that the prior art may anticipate only if there is total

[171] *See* text accompanying notes x-y *supra*.
[172] *See* text accompanying notes x-y *supra.*
[173] *See* text accompanying notes x-y, *supra*.
[174] *In re* Hogan, 559 F.2d 595 (C.C.P.A. 1977); Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Fed. Cir. 2003).
[175] *See* Chiron Corp. v. Genentech, Inc., 363 F.3d 1247 (Fed. Cir. 2004) ; *cf.* Schering Corp. v. Amgen Inc., 222 F.3d 1347 (Fed. Cir. 2000).

lack of knowledge by those skilled in the art but not if the level of knowledge is such that the element was desired but difficult to obtain.[176]

If decided based on written description, some cases would suggest that the prior art may anticipate despite lack of knowledge by those skilled in the art[177] while others would suggest that this is not the case.[178] And again, one case would suggest prior art may anticipate only if there is total lack of knowledge by those skilled in the art but not if the level of knowledge is such that the element was desired but difficult to obtain.[179] Those who hold patents or challenge them could be assured only of a complete inability to predict the answer to the question.

Most importantly, the convergence of these areas demonstrates the futility of addressing the issue piecemeal. The courts cannot simply resolve, for example, whether inherency includes unrecognized elements. Any decision there, no matter what, leaves conflicts in the areas of written description, claim construction, and enablement that will wrap back around into the inherency inquiry.

The temptation to define prior art as including inherent elements is strong. It provides the instant gratification of shutting down certain types of ever greening. [180] That satisfaction, however, comes at the cost of exacerbating chaos across the doctrines.

From another perspective, Dan Burk and Mark Lemley have suggested that the inherency cases can be understood differently from the way in which they are currently interpreted in the

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[176] *See* Chiron Corp. v. Genentech, Inc., 363 F.3d 1247 (Fed. Cir. 2004) ; Plant Genetic Sys. v. Dekalb Genetics Corp., 315 F.3d 1335 (Fed. Cir. 2003).
[177] *See* Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Fed. Cir. 2003).
[178] *Cf.* Schering Corp. v. Amgen Inc., 222 F.3d 1347 (Fed. Cir. 2000). .
[179] *See* Chiron Corp. v. Genentech, Inc., 363 F.3d 1247 (Fed. Cir. 2004)
[180] *See* Derzko [add full cite] at 221 (noting that the *Schering* case will eliminate some types of metabolite claims and that to the extent metabolite claims constitute evergreening, the case will dampen incentives for certain forms of evergreening).

field.[181] According to the authors, the cases actually turn on whether society is already using and getting the benefit of an element, not whether the element was unrecognized[182] In other words, the rule should be that if the public already benefits from an invention, even if they don't know about it, that invention is inherent in the prior art.[183]

The public use and benefit rule has the advantage of threading a line carefully through some of the trickier inherency cases.[184] Problems with the approach emerge, however, when doctrines throughout the area are considered as a whole.

For example, recall that in *Schering*, a pharmaceutical company tried to extent its patent on a drug by patenting the compound formed by the patient's body when the drug was digested.[185] The public use and benefit rule would deny a patent on the compound. The theory would be that the compound was already being formed in the body, and the public, at least those taking the drug, already had the benefit of it.

The pharmaceutical company's invention, however, looks very much like many of the gene and protein inventions that commonly receive patents. For example, the pharmaceutical company determined that the body formed a substance. The company isolated and purified the

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[181] *See* Dan L. Burk & Mark A. Lemley, *Inherency* 3 (arguing that confusion in inherency law is unnecessary given that the facts of the inherency cases offer a simple way to understand them) (unpublished manuscript on file with author).
[182] *See id.* at 4
[183] *See id.* (outlining a proposed public benefit test).
[184] For example, the rule forbids patenting a metabolite formed in the process of ingesting an earlier drug but allows patenting a byproduct formed in the process of producing an earlier invention where the byproduct was discarded as a waste product. *Compare id.* at 11-12 (describing Schering Corp. v. Geneva Pharm., 348 F.3d 992 (Fed. Cir. 2003) *with id.* at 5-6 (describing Tilghman v. Proctor, 102 U.S. 707 (1880)) and 14 (describing Edison Elec. Ligh Co. v. Novelty Incandescent Lamp Co., 167 F. 977 (3d Cir. 1909)). Thus, the rule brings into harmony some difficult cases.
[185] *See* Schering Corp. v. Geneva Pharms. Inc., 339 F.3d 1373, 1375-76 (Fed. Cir. 2003).

substance, identified its structure and biologic properties, and then applied for a patent on the substance.[186]

Many patents for genes and proteins are based on the same type of work. An inventor determined that the body formed a substance, a protein for example. The inventor isolated and purified the substance, identified its structure, determined a use, and then applied for a patent on the substance.

Although such protein patents are routinely granted, the logic of the public use and benefit rule, would deny patenting under the circumstances. After all, the production of the protein is "inherent" in the prior art of the human body. People are already making, using, and receiving the benefit of the protein in their bodies, even if no one skilled in the art knows about it. If the body's formation of the *Schering* metabolite leads to inherency, so should the body's formation of the protein. From the logic of the proposed rule, therefore, the protein, and an astounding array of other biospace inventions, would be unpatentable.[187]

One could try to argue that there is something different about a compound formed in the body in response to an external substance like a chemical. The human body, however, is constantly interacting with external substances – foreign agents, toxins, viruses, bacteria. The entire field of antibody products is based on taking a substance that the body has developed, often in response to an external agent, isolating it, and replicating it outside the body. Regardless of whether we are discussing antibodies or drug metabolites, both are organic substances developed by the body in response to external substances. If one were to argue that the metabolite is

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[186] *See* Schering Corp. v. Geneva Pharms. Inc., 348 F.3d 992, 993 (Newman, J. dissenting from denial of rehearing en banc).

[187] *Cf.* Schering Corp. v. Geneva Pharms. Inc., 348 F.3d 992, 993 (Newman, J. dissenting from denial of rehearing en banc). (objecting to the rule that prior art can anticipate even as to unknown

unpatentable because we should look differently when the body creates something in response to an external substance, then many antibodies would be unpatentable as well.

The public use and benefit rule also suffers from the same problem as the broader inherency rule. Although the public use and benefit rule offers the prospect of reigning in patent holders by limiting their ability to reach backward, it has the perverse effect of increasing their ability to reach forward.

Specifically, when examining a piece of prior art to decide whether a later invention is anticipated, the proposed rule would hold that the piece of art includes things inherently in use, even if no one knows about those things. If that piece of prior art is something on which another inventor holds a patent,[188] however, the inventor of that piece of prior art also should be able to claim that the invention includes things inherently in use. After all, how can we hold up a sphere and say, "when we look at it from one direction it is an apple, and when we look at it from another direction it is an orange"? Either the invention includes the unknown element or it does not.

Following the logic of the proposed rule, therefore, all inventions would reach to things inherently in use – even if those elements could not be recognized by anyone in the field and were not described or enabled by the inventor. This is a remarkably expansive view of the footprint of an invention.

We could, of course, draw artificial lines. We could declare that on the one hand, when an inventor creates something with unknown qualities and we are trying to determine the inventor's rights, we will say that the invention does not reach those qualities. On the other hand, when an inventor creates something with unknown qualities and we are trying to determine the

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elements and asking if the panel intends that no newly discovered product found in an organism can be patented).

rights of *other* inventors, we will say that the scientist's invention *does* reach those qualities. This approach is offered by the authors to rationalize the asymmetries created by the proposed rule.[189]

Along the same lines, we could determine that terms like "enablement" have slightly different meanings in different circumstances. This approach also is suggested by the authors to wrestle with some of the additional conflicts in the doctrines.[190]

If we create different definitions that are to be applied by looking from different directions, however, these definitions are likely to wrap around and collide with each other. In fact, that is precisely what is happening in the Federal Circuit now as doctrines established in isolation expand and collide. Such collisions are bound to occur because conceptually, we are asking the same question: Does the footprint of something that exists reach to things unknown?

Patent law can, and must, develop a consistent image of the footprint of an invention. Without that, we cannot hope to produce a coherent body of law that can be understood by inventors, judges, and juries alike. If we simply add greater twists and turns of complexity without resolving the conceptual question, we will do no more than exacerbate the current chaos in the doctrines.

III. Defining the Footprint

As described above, the Federal Circuit starts out on the path to chaos with cases like *Hoerchst* and *Hogan* that allow patent holders to reach broadly into the unknown. *Hoechst*

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[188] Prior art can be something unpatented such as a substance found in nature, but prior art is often something on which other inventors hold a patent.
[189] *See* Burk & Lemley, *Inherency*, *supra* note x, at 27 (noting that the result, while seemingly odd in its asymmetry, makes sense as a policy matter).
[190] *See id.* at 17 (interpreting enablement cases to conclude that the standard for enablement is somewhat different in different circumstances).

does this through general pronouncements of the reach of an invention as well as through specific applications of the enablement and written description rules. *Hogan* does this simply through application of the enablement rule.

In later opinions, judges bob and weave, trying to avoid the implications of doctrines that lead to puzzling and uncomfortable results. *Schering* adopts a highly strained reading of the claims. *Plant Genetic Systems* crafts a strange line in which a patent holder can reach some, but not all, things unknown.[191] The *Chiron* court echoes *Plant Genetic Systems* but then uses another doctrine to completely eliminate a patent holder's ability to reach *anything* unknown.[192]

Similar patterns emerge in the inherency cases concerning whether new inventions should be blocked by interpreting prior art to include things unknown. Some cases hold that prior art includes things unknown. Others disagree. Finally, the *Elan* court tries to avoid the conflict by throwing prior art questions into the mess of the enablement doctrine.

The better path is to acknowledge that cases like *Hoechst* and *Hogan* are grounded in theories that are incompatible with the uncertain arts. Given how little we know about each biospace invention, granting rights to all embodiments, and everything contained therein, projects an enormous shadow across the future, one whose size cannot even be contemplated at the time of the invention.

For uncertain arts such as biotechnology, we should discard the notion that the basic definition of an invention includes things that could not have been known at the time of the invention. Rather, an invention should be defined in light of the art at the time.

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[191] *See* Plant Genetic Systems v. [add full cite] (holding that a patent holder can reach things that could not have been contemplated in the art at the time of the invention but not to things desired but difficult to obtain).

Framing the inquiry in this way not only makes sense theoretically, it also enhances doctrinal coherence. After all, much of the current disarray has developed as courts strain against the sweeping implications of allowing biospace inventions to reach into unknown territory. Establishing that the basic definition of an invention arises in light of the art at the time of the invention can resolve the overt doctrinal conflicts as well as the more subtle inconsistencies in the directions suggested by the doctrines.

This theoretical perspective would play out across the doctrines in the following manner. In claim construction, claims would be interpreted in light of the art at the time of the invention, and there would be no need for the type of strained interpretation applied in *Schering*. In enablement and written description, a patent holder could not reach embodiments unknown at the time of the patent. This would eliminate the strange enablement rules in which a patent holder can reach to some but not all things unknown, rules which have perverse incentives and are then completely undone by certain versions of the written description doctrine. Finally, in the doctrine of inherency, a prior art reference could not anticipate if the element could not have been recognized by those skilled in the art at the time. In short, defining inventions in light of the state of the art at the time would resolve the surface inconsistencies as well as the conflicting undercurrents described above.

This approach would not necessarily confine an inventor's rights precisely to what was done by the inventor. I am suggesting that patents should be interpreted in light of the art at the time, not simply limited to the precise words and paths of the inventor.[193] Thus, an inventor potentially could reach beyond the precise work completed to what could be accomplished given

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[192] *See supra*, text accompanying notes x – y (describing the *Chiron* case and noting its failure to follow *Hoechst*).

what scientists know at the time. An inventor, however, could not reach to things that could not have been accomplished or were unknown in the art at the time.

A. Should the Rules be Different for the Doctrine of Equivalents?

An inventor's rights are delineated not only by the footprint of the invention, but also by the doctrine of equivalents. With the doctrine of equivalents, a patent holder can argue that although the accused product is not what the patent holder created, it should, nonetheless, be considered equivalent.[194] Although the current chaos involves doctrines related to defining an invention and determining whether an accused product directly infringes that invention, similar issues could arise under the doctrine of equivalents.

The doctrine of equivalents provides some breathing space to protect against those who make trivial changes that the patent holder could not have anticipated. It is a safety net that has been applied sparingly by the courts.[195] In particular, the courts have stressed that the doctrine of equivalents must be applied by asking whether each element of the accused product is the same or equivalent to each element of the patented product, not by looking at the products overall.[196]

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[193] *See* Feldman, *The Inventor's Contribution, supra* note x, at text y (arguing that disclosure may include things not directly expressed but known in the art at the time).
[194] *See* Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950); Anthony A. Azure, *Festo's Effect on After-Arising Technology and the Doctrine of Equivalents*, 76 WASH. L. REV. 1153, 1157-58 (2001).
[195] *cf.* Hilton Davis Chemical Co. v. Warner-Jenkinson Co., Inc. 62 F.3d 1512, 1518 (Fed. Cir 1995) (en banc), *rev'd and remanded*, 520 U.S. 17 (1997) (stressing that the defining principles of any doctrine of equivalents formulation should include a focus on individual elements and a special vigilance against allowing equivalence to completely eliminate any such concepts).
[196] *See* Hilton Davis Chemical Co. v. Warner-Jenkinson Co., Inc. 520 U.S. 17, 40-41 (1997) (explaining that the defining principles of any doctrine of equivalents formulation would include a focus on individual elements and a special vigilance against allowing the concept of equivalence to eliminate completely any such elements).

In this context, the Supreme Court has hinted that it might be receptive to considering unknown embodiments in a doctrine of equivalents inquiry. The suggestion appeared in the *Festo*[197] case in 2002. *Festo* concerned a limitation on the doctrine of equivalents that prevents patent holders from reclaiming through equivalence what they gave up at the Patent and Trademark Office in order to obtain a patent.[198] The limitation, known as prosecutorial history estoppel, holds generally that a patentee's decision to narrow claims through amendments at the Patent and Trademark Office is presumed to be a general disclaimer of territory. That territory cannot be reclaimed through the doctrine of equivalents.[199]

In *Festo*, the Supreme Court listed exceptions in which an amendment cannot reasonably be viewed as surrendering a particular equivalent. The list of exceptions included circumstances in which the applicant could not have foreseen the development of the equivalent

One could argue that the Supreme Court decision in *Festo* should best be understood in the limited context of knowing relinquishment. The message of *Festo* may be that a patent holder cannot be held responsible for *knowing* relinquishment of something that the inventor could not have known about. Nevertheless, it could also be read as signaling the Court's willingness to allow consideration of unknown embodiments in the limited context of a doctrine of equivalents analysis. Thus, *Festo* at least raises the question of whether an inventor should be able to reach beyond the state of the art for the purposes of applying the doctrine of equivalents.

The doctrine of equivalents, however, is far too amorphous and uncertain to provide the necessary logic and clarity on this issue. Courts have failed to reach agreement on the verbal formulation of the test, let alone on how the test should be applied in various settings. For

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[197] Festo Corp., v. Shoketsu, 535 U.S. 722 (2002).
[198] *See id.* at __.
[199] *See id.* at 740-41.

example, the test is described in some Federal Circuit cases as whether each element of the accused device serves the same function, in the same way, to obtain the same result as the patented device.[200] Other Federal Circuit cases describe the test as whether the differences between the two inventions are insubstantial.[201] The Supreme Court has declined to resolve the debate, holding instead that different linguistic formulations may be suitable for different cases depending on the facts and leaving it to the Federal Circuit to refine the test in its sound judgment.[202] The Federal Circuit has yet to meet the challenge, and it remains one of the most uncertain areas of patent law.

Any logic, clarity, and consistency created by limiting an invention to the state of the art at the time could be completely unraveled by revisiting the issue in the uncertain and undisciplined realm of the doctrine of equivalents. In its current form, therefore, the doctrine of equivalents could recreate chaos throughout this area of patent law if it is applied in more than rare circumstances.

IV. Conclusion

Basic doctrines, carried over by analogy to mechanical inventions, would define an invention broadly to include embodiments and aspects of the invention that were unknown at the time of the invention. In fields of great uncertainty, however, we cannot define an invention to include the unknown without granting an extraordinarily expansive reach to inventors, far beyond what the inventor may have contributed. The temptation to restrain that reach has lead to strange doctrinal twists and an unworkable body of law.

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[200] *See, e.g.,* Genentech, Inc. v. The Wellcome Foundation, 29 F.3d 1555, 1567 (Fed. Cir. 1994).
[201] *See* Hilton Davis Chemical Co. v. Warner-Jenkinson Co., Inc. 62 F.3d 1512, 1518 (Fed. Cir 1995) (en banc), *rev'd and remanded*, 520 U.S. 17 (1997).
[202] *See* Hilton Davis Chemical Co. v. Warner-Jenkinson Co., Inc. 520 U.S. 17, 40-41 (1997); *see also* 5A CHISUM, *supra* note x, at § 18.02[5].

In particular, across 5 disparate doctrines, current cases related to the footprint of a biospace invention pull in different theoretical directions and stand in contradiction to each other. Judges are unable to resolve the dilemmas because the basic theory underlining this doctrinal area is unsound.

To resolve these problems, we must establish a clear and consistent vision of the definition of an invention, one that can be understood by both the governing and the governed. Defining an invention in light of the art at the time of the invention brings coherence to this area of law and eliminates the need for the contorted doctrines that have developed in the field.