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REACH-THROUGH CLAIMS IN THE AGE OF BIOTECHNOLOGY

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TABLE OF CONTENTS

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INTRODUCTION

The 21st century may come to be known as the Age of Biotechnology in much the same way that the end of the 20th century became known as the Information Age. However, while innovations in the field of biotechnology have great potential, biotechnology carries high business risk with its possibility of high reward.[1] Companies are investing approximately $400-500 million in researching, developing, and bringing to market new technologies that will raise people's standard of living, improve quality of life, reduce suffering, and promote longevity.[2] These companies need to protect their investments from encroachment by their competition.[3] Since patents provide the strongest form of intellectual property protection, obtaining such security is playing an ever-increasing role in the business decisions of companies investing in biotechnology.[4]

I. BUSINESS AND TECHNOLOGICAL REALITIES IN THE WORLD OF BIOTECHNOLOGY

The beginning of the 21st century marks the dawn of a new era with a universe of possibilities for researchers in the field of biotechnology. In large part, the number of avenues open for

1. *See* Robert Bazell et al., *Biotechnology in 2018: How Will Genetic Science and Technology Change the World?*, 21STC, Fall 1998 (stating that biotechnology has become "synonymous over the years with very high risk and high reward"), *at* http://www.columbia.edu/cu/21stC/issue-3.3/forum_all.html.

2. *See* Biotechnology Industry Organization (BIO), *Primer: Genome and Genetic Research, Patent Protection and 21st Century Medicine* 18 (July 12, 2000) (noting the average industry investment in a drug totals $500 million or more), *available at* http://www.bio.org/genomics/primer.html; John K. Borchardt, *The Business of Pharmacogenomics,* 4 MOD. DRUG DISCOVERY 35 (July 2001) (estimating an average investment of $500 million to bring a drug to market), *available at* http://pubs.acs.org/subscribe/journals/mdd/v04/i07/html/07borchardt.html; William A. Haseltine, *The Promise of Genomics*, *in* CONVERGENCE, THE BIOTECHNOLOGY INDUSTRY REPORT 6 (Ernst & Young, LLP, Millennium ed. 2000) [hereinafter CONVERGENCE] (reporting that the cost of developing a new drug is $400 million), *available at* http://www.ey.com/global/vault.nsf/US/Biotech%5F%5FConvergence%5F%2D%5FFull%5FReport/%24file/O00254.pdf.

3. *See* BIO, *supra* note 2, at 28 (emphasizing that while a patent does not guarantee a profit, it does prevent competitors from copying the patent holder's development and undercutting the potential price of the innovation).

4. *See* Charles Craig, *Current Public Policy Challenges*, *in* CONVERGENCE, *supra* note 2, at 65 ("Without patents . . . there would be no biotech industry and no innovative drug development."); *see also IP—The Prize in the Attic*, LEGAL TIMES, June 11, 2001, at 18 (noting how companies are coming to recognize their intellectual property as an "important and relatively untapped asset").

exploration is due to significant breakthroughs in methodologies in the gene and protein based areas of pharmaceutical chemistry.[5] During the 20th century, the scientific method[6] was the controlling modality in innovation. Specifically, scientists first recognized a problem, developed an approach to study the problem, and then worked to create specific and particular modes of dealing with the problem.[7] For example, in disease treatments, the first step was to understand the underlying defect associated with the condition under consideration.[8] This step involved both biochemical and genetic analysis—determining the biochemical defect and physiological consequence of this defect and what, if any, genetic basis correlates to the defect.[9] Scientific inquiry started with a defined endpoint—the treatment or diagnosis of a particular disease or condition.[10] In recent years, however, this approach has been supplemented by a less directed approach that has been made possible by advances in computing, data collection and visualization tools, and combinatorial technologies.[11]

5. *See* Georg C. Terstappen & Angelo Reggiani, *In Silico Research in Drug Discovery*, 22 TRENDS IN PHARMACOLOGICAL SCIENCES 23, 23 (2001) (reflecting that the introduction of genomic sciences has rendered biology the "main driver" in the discovery of novel drugs, even in comparison to chemistry and pharmacology). Drug discovery programs often integrate genomics, protein sciences, and high throughput screening to identify compounds that show promise of therapeutic application. *See* Eliot H. Ohlstein et al., *Drug Discovery in the Next Millenium,* 40 ANN. REV. PHARMACOLOGY & TOXICOLOGY 177, 188 fig.3 (2000) (presenting a graphic representation of the drug discovery progression from molecular targets to novel therapeutics); *see also* James A. Landro et al., *HTS in the New Millennium: The Role of Pharmacology and Flexibility*, 44 J. PHARMACOLOGICAL & TOXICOLOGICAL METHODS 273, 273 (2000) (discussing the several aspects of discovery: "target identification (genomics and molecular biology groups); reagent preparation (protein expression and purification groups); and compound management, assay development, and high throughput library screening (lead discovery groups)").

6. *See generally The Scientific Method—Elegant Experiments,* ACCESS EXCELLENCE @ THE NATIONAL HEALTH MUSEUM (1999) [hereinafter *Scientific Method*] (stating that the scientific method is founded on the principles of cause and effect), *available at* http://www.accessexcellence.org/AB/BC/ Elegant_Experiments.html.

7. *See id.*

8. *See, e.g.*, Paul Berg, *Reverse Genetics: Its Origins and Prospects*, 9 BIOTECH. 342, 343 (Apr. 1991) (describing the classical genetics approach as proceeding "from the phenotype (disease) to identifying the responsible gene's chromosomal locus, then to recovering the gene, and finally to discovering the mutational alteration that accounts for the disease").

9. *See* NATIONAL HUMAN GENOME RESEARCH INSTITUTE FACTSHEET: DISEASE GENE DISCOVERY 1 (Oct. 1997) (recalling that in the past "scientists needed some idea of the biochemical errors of a disease before they could search for its genetic basis"), *available at* http://www.nhgri.nih.gov/Policy_and_public_affairs/Communications/ Fact_sheets/Disease_gene_discovery.pdf.

10. *See, e.g.*, *Scientific Method*, *supra* note 6 (explaining that scientists searched for and discovered the cause of AIDS before searching for a remedy).

11. *See generally* Jeffrey Hanke, *Genomics and New Technologies as Catalysts for Change*

For example, the science of combinatorial chemistry allows the generation of complex libraries of chemical compounds that can be simultaneously assayed, to screen for target molecules that exhibit properties of interest.[12] Some of these libraries are based upon particular core structures to which a myriad of substitutions are made, while in others, many different core structures along with their derivatives are combined.[13] The selection of which cores and what substitutions are made is often determined by a desire to affect a particular biological function and to test promising chemical analogues.[14] In other circumstances, the libraries are prepared with no particular target or activity in mind.[15]

In nucleic acid sequencing, as recently as twenty years ago it might have taken a scientist months to sequence a particular genomic or cDNA[16] molecule.[17] In recent years such sequencing has been automated using banks of highly sophisticated computers[18] allowing on the order of millions of bases of a nucleic acid sequence to be determined in a single day.[19] The principal limitations today are the

in the Drug Discovery Paradigm, 28 J.L. MED. & ETHICS 15 (2000) (presenting an overview of new technologies in the fields of informatics, molecular biology, combinatorial chemistry, and high throughput screening that offer new means to process the mass of information emerging from genomic sequencing and translate it into tangible treatments for human diseases).

12. *See* Stu Borman, *Combinatorial Chemistry: Industry is Embracing the Technology 'Totally,' as Researchers Continue to Advance the Art of Rapid Synthesis and Screening*, CHEMICAL & ENGINEERING NEWS, Apr. 6, 1998 (discussing how almost all pharmaceutical companies have embraced this innovation within the last ten years), *available at* http://pubs.acs.org/hotartcl/cenear/980406/comb.html.

13. *See id.* (discussing how pharmaceutical companies create their libraries).

14. *See, e.g.*, Stu Borman, *Reducing Time to Drug Discovery*, CHEMICAL & ENGINEERING NEWS, Mar. 8, 1999 (describing a combinatorial research project that identified non-peptide agonists for each of five different somatostatin receptor types by starting with small molecules similar in structure to a somatostatin agonist and then using the compound with the highest binding affinity as a template for library construction), *available at* http://pubs.acs.org/hotartcl/cenear/990308/comb1.html.

15. See Borman, *supra* note 12, for an overview of several techniques for producing combinatorial libraries.

16. "cDNA" is complementary deoxyribonucleic acid.

17. *See* Edward N. Trifonov, *Earliest Pages of Bioinformatics*, 16 BIOINFORMATICS 5, 6 (2000) (discussing the first painstaking sequencing efforts, which involved the application of chemical, enzymatic, and spectral analysis techniques to every single base step, and the breakthrough of "read-the-gel" techniques, which allowed for the sequencing of 200 nucleotides in a month).

18. Significant improvements in technologies related to genome analysis include automated sample handling systems, instrumentation for high throughput sequencing, and more efficient computational tools for analysis of sequence data. *See* Fredrik Sterky & Joakim Lundeberg, *Sequence Analysis of Genes and Genomes*, 76 J. BIOTECH. 1 (2000) (providing an overview of advances in sequencing methods and strategies).

19. *See, e.g.*, Elkin, C.J. et al., Abstract, *High-Throughput Plasmid Purification for*

amount of physical and financial resources that can be applied to obtaining raw sequence data and analyzing the data to properly annotate and characterize it.[20]

Whether discussing combinatorial chemistry or nucleic acid sequencing, the end result is the same—the generation of a large number of compounds or databases that theoretically would be useful in some context.[21] The question, of course, is in what context? Medical texts list hundreds of diseases that have both biochemical and genetic bases.[22] Medicine's goal is to elaborate diagnostics and treatments. With the advent of large numbers of combinatorial libraries, it is probable that useful pharmacological agents have been made.[23] The difficulty is in determining which ones they are and what they do. An enormous pool of information has been created,[24] but establishing links between genes and disease will take decades.[25]

One difficulty in the fields of genomics[26] and proteomics[27] is

Capillary Sequencing, 11 GENOME RESEARCH 1269 (2001) (stating that the Joint Genome Institute has reached an average throughput of 18.3 million bases per day); *Researchers Unravel Genome for 'Superbug' Bacterium Using One Day's Production Capacity*, LAWRENCE LIVERMORE NATIONAL LABORATORY (May 8, 2000) (heralding that scientists sequenced 2.8 million base pairs of DNA of the genome of *E. faecium* using a single day's production capacity at the Department of Energy's Joint Genome Institute's Sequencing Facility), *available at* http://www.llnl.gov/llnl/06news/NewsReleases/2000/NR-00-05-02.html.

20. *See* Press Release, European Molecular Biology Laboratory/Sanger Centre, Taking the Next Step with the Human Genome: Wellcome Trust Announces Major Investment in Genome Bioinformatics (July 20, 2000) (discussing the center's new database for the human genome that was created to address the need for physical resources), *available at* http://www.EMBL-Heidelberg.DE/ExternalInfo/oipa/article1. pdf. For an overview of a number of tools available to help analyze the sequence data, see David J. Galas, *Sequence Interpretation: Making Sense of the Sequence*, 291 SCI. 1257 (Feb. 16, 2001), *available at* http://www.sciencemag.org/cgi/content/full/291/5507/1257.

21. *See, e.g.*, Hanke, *supra* note 11, at 15 (discussing how combinational chemistry or nucleic acid sequencing can potentially help doctors identify a gene mutation before the onset of a disease).

22. *See, e.g.*, CECIL TEXTBOOK OF MEDICINE (Wyngaarden, J.G. & Smith, L.H. eds., 1988).

23. *See* Borman, *supra* note 12 (noting the progress pharmaceutical companies are making in developing these libraries).

24. *See* Ohlstein et al., *supra* note 5, at 177-91 ("The sheer volume of genetic information being produced has shifted the emphasis from the generation of novel DNA sequences to the determination of which of these many new targets offer the greatest opportunity for drug discovery.").

25. *See Disease Gene Pairing Points to Future,* BBC NEWS (Sept. 21, 2001) (emphasizing the difficulty in finding the causes of diseases that are linked to as many as six or more mutated genes working together), *available at* http://news.bbc.co.uk/hi/english/health/newsid_ 1555000/1555117.stm.

26. *See* PHARMACEUTICAL RESEARCH AND MANUFACTURERS ASSOCIATION OF AMERICA'S GENOMICS LEXICON (defining genomics as "the study of genes and their function"), *at* http://genomics.phrma.org/lexicon/g.html (last updated Jan. 24, 2002).

determining which protein is useful for treating what disease, and which gene correlates with what disease.[28] Scientists and companies require vast sums of money and resources to make those determinations, but the failure rates in the biotechnology industry are extraordinary.[29] For example, in the pharmaceutical industry, for every 5,000 to 10,000 compounds screened there are about 250 lead candidates in pre-clinical testing, and of these, only one is likely to become a Food and Drug Administration (FDA) approved drug.[30] It may take as long as thirteen years from initial screening to FDA approval, thereby hindering any quick return on investment.[31]

In order to make it worthwhile to expend the time, energy, and monetary resources necessary for such a research and development effort, and to counterbalance the significant risk involved in such an undertaking, products that make it to market must reap significant profits. Many companies in the biotechnology industry are supported by venture capital,[32] which is consumed at a high burn rate;[33] long-term investors are needed because it may be a very long time before any return on the initial investment is realized.[34] Thus,

27. *See* THE BIOSPACE GLOSSARY (defining proteomics as the "study of gene expression at the protein level, by the identification and characterization of proteins present in a biological sample"), *at* http://www.biospace.com/gls_detail.cfm?t_id=62604 (last visited Jan. 24, 2002). For a description of the basic science behind genomics and proteomics, see *The Science Behind the Human Genome Project, From the Genome to the Proteome,* HUMAN GENOME PROJECT, *available at* http://www.ornl.gov/hgmis/ project/info.html (last modified Dec. 7, 2001).

28. *See Disease Gene Pairing Points to Future*, *supra* note 25 (discussing the difficulty of finding the causes of diseases that are linked to as many as six genes working in combination and therefore developing treatments); *see also National Human Genome Research Institute Factsheet: Disease Gene Discovery*, *supra* note 9, at 2-3 (explaining the difficulty that scientists face as they move away from studying "single-gene" disorders).

29. *See, e.g.*, Hanke, *supra* note 11, at 17 (acknowledging that following up on as many as 10,000 targets worthy of pursuit for drug discovery will be hugely expensive). Pharmaceutical companies spend between 1.8 and 4 billion dollars annually on research and development, yet only one in 100 discoveries yields a product. *See id.*

30. *See The Product Pipeline: Progress and Potential in* CONVERGENCE, *supra* note 2, at 47 (providing a graphic representation).

31. *See id.* at 46 (discussing the lengthy process of drug approval within the pharmaceutical industry).

32. *See* Paula Park, *Climbing the Money Tree*, THE SCIENTIST, Nov. 26, 2001 (stating that venture capitalists invested about $260 million per quarter in 2001; $358 million per quarter in 2000; $144 million per quarter in 1999), *available at* http://www.the-scientist.com/yr2001/nov/prof2_011126.html; *see also App. 1*, *in* CONVERGENCE, *supra* note 2, at 74 (noting that from July 1998 to June 2000, venture stage financing in the biotechnology industry totaled $3.1 billion).

33. The burn rate is the amount of money necessary for product research and development. *See* Peg Brickley, *The 'Uncompany' Answer to Building a Company*, THE SCIENTIST, Aug. 20, 2001, *available at* http://www.thescientist.com/yr2001/aug/prof2_010820.html.

34. *See* Nadia S. Halim, *Investing in the Future: Innovative Technologies*, THE

companies need to leverage technological innovation to garner sustaining investments.[35] In order to raise the necessary funds, companies need to be as forward thinking as possible during the research and development phase.[36] As a result, start up companies find it critically important to obtain intellectual property rights to their technological innovations to boost interest from the investment community and thereby attract the sustaining capital required for their survival.[37] Patents attract the necessary venture capital for these highly entrepreneurial companies to bring their dreams to reality.[38]

Companies in biotechnology related industries are accustomed to taking business risks, but should they be taking comparable risks on the legal side in the search for intellectual property protection? A fine balance exists between obtaining the maximum protection afforded and crossing over the invalidity line. A patent must be both a sword[39] and a shield.[40] Effective patent protection wards off

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SCIENTIST, Aug. 30, 1999, *available at* http://www.thescientist.com/yr1999/august/halim_p8_990830.html. While venture capitalists typically look for a two-to-four year period for a return on investments, biotech investments may require three times longer to yield any return, thus long-term investors are necessary. *See id.*

35. For a general discussion of converging technology platforms (e.g., information technology approaches applied to biochemistry) and converging market strategies in the biotechnology industry, see Brian Sager, *Strategic Drivers of Converge*, *in* CONVERGENCE, *supra* note 2, at 26. Recently, biotechnology companies have converged with high technology companies in order to capitalize on those non-biotechnological innovations, thereby creating a hybrid marketplace that builds upon the industries' technology, strategies, and business plans. *See id. See also Convergence: A Technology Explosion*, *in* CONVERGENCE, *supra* note 2, at 17 (commenting on the growing shift in the biotechnology industry away from the unified research and development model, toward "a matrix of supply chain relationships along the drug discovery process, with increasing reliance on technology alliances and partnerships" (quoting Alex To, Head of Biotechnology Research Group, Credit Suisse First Boston)).

36. *See* Peg Brickley, *Protecting Intellectual Property*, THE SCIENTIST, Oct. 29, 2001 (advising that researchers should contact a patent lawyer before the invention is even finished), *available at* http://www.the-scientist.com/yr2001/oct/prof2_011029.html.

37. Rebecca Eisenberg, *Patenting Research Tools and the Law*, *in* INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY 6 (Nat'l Academy Press 1997) [hereinafter *Patenting Research Tools*] (seeking, for example, patents on inventions long before those inventions are incorporated into marketable products), *available at* http://stills.nap.edu/ html/property/2.html#chap2. Note that while young firms need patents to recruit investors, established firms seek patents so that they may dominate a market and raise the money necessary for clinical testing. *See id.*

38. *See* Park, *supra* note 32 (reviewing the annual venture capital investment in the pharmaceutical industry).

39. A patent is used as a sword when the patent owner asserts the right to exclude others from making, using, selling, offering for sale, or importing into the United States the patented invention. *See* 35 U.S.C. § 154(a)(1) (2001) ("Every patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using, offering for sale, or selling the invention . . . ").

40. A patent functions as a shield by disclosing the patentee's invention to the

competitors from invading a company's space in the marketplace while helping to defend one's freedom to operate against competitors' challenges.[41] Competitors may seek to undermine the patent because it serves as a tollgate preventing others from acting freely in the market place.[42] Thus patents play a crucial role in the world of biotechnology.

II. REACH-THROUGH PATENT CLAIMS

The central purpose of the intellectual property system is set forth in the U.S. Constitution. Article I, Section 8, clause 8 gives the Congress power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their Respective Writings and Discoveries."

The Founding Fathers of this nation felt strongly that rewarding innovation in exchange for public disclosures would make the country prosper.[43] Each new discovery builds upon the foundation laid by those that came before it.[44] This concept is built into the U.S. Patent statutes. As stated in 35 U.S.C. § 101: "Whoever 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 therefor, subject to the conditions and requirements of this title."

Courts addressing patent infringement claims often struggle to determine the appropriate boundary separating a suitable scope of protection for what has been invented and disclosed to the public from that which an inventor has not yet put into the public domain.[45]

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public, thereby preventing a competitor from obtaining a patent on the same subject matter or an obvious variant thereof. *See id.* §§ 102-103.

41. *See id.* § 154 (extending no right to make or use one's invention, only the right to exclude others from the invention).

42. *See, e.g.*, Gregory J. Kirsch, *Strategies for the Use of Patents by Start-up Internet Companies* 4 (characterizing the patent as a toll), *at* www.gigalaw.com/articles/2000/kirsch-2000-07.html (July 2000).

43. *See, e.g.*, Reps. Ed Bryant & Jim McDermott, *Patent Integrity Fuels American Prosperity* (arguing that Article I, section 8, clause 8 makes a "simple, straightforward and unmistakably clear" statement that the Founding Fathers believed that innovators should benefit from their labors), *at* http://www.house.gov/bryant/claritinoped.html (last visited Jan. 21, 2001).

44. *See id.* (explaining that benefits for inventors provide the incentive to create new products that benefit everyone).

45. *See* Markman v. Westview Instruments, Inc., 517 U.S. 370, 388, 38 U.S.P.Q.2d (BNA) 1461, 1470 (1996) (noting that patent construction is a "special occupation" that should be handled by judges who, by virtue of "special training and practice," are more likely to give a "proper interpretation" to such highly technical patent claims).

The determination of this boundary is especially problematic in the highly unpredictable areas of biotechnology and pharmaceutical chemistry.[46] This may be particularly troublesome where patents contain prophetic disclosures while claiming exclusive rights to all uses of the patented item.[47] For example, in biomedical research the discovery of a new cell receptor[48] that controls physiological events in the human body may lead to the use of the receptor as a therapeutic agent. The receptor also may result in the future discovery of compounds such as hormones that activate the receptor or that inhibit the receptor. Such future discoveries may be made when the new receptor is used as a screening reagent in assays to identify and purify previously unknown hormones.[49]

In this example, the inventor might claim the new cell receptor as a product because it can be used as a pharmaceutical.[50] However, an inventor might also try to claim the new cell receptor for use in a process for making future discoveries, e.g., a tool used in screening assays that detect previously unknown hormones.[51] There can be significant differences between the future discoveries or inventions that incorporate an original invention and those future discoveries or

46. *See, e.g.*, Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1374, 52 U.S.P.Q.2d (BNA) 1129, 1138 (Fed. Cir. 1999) (dismissing a patent infringement claim in part because the patent did not provide sufficient guidance or specificity to the public to meet the enablement test). Courts wrestle with the problem that judges, who rarely have relevant technical backgrounds, are charged with construing patent claims to complex inventions in highly technical arts. *See, e.g.*, Cybor Corp. v. FAS Tech. Inc., 138 F.3d 1448, 1454, 46 U.S.P.Q.2d (BNA) 1169, 1173 (Fed. Cir. 1998) (en banc) (determining the proper standard of review for findings of fact made by the district court in patent claims and the proper role of extrinsic evidence in constructing the scope of those claims). In *Cybor Corp.*, the Federal Circuit split over the proper standard of review for factual findings made by the lower court, with two judges concurring with the majority and two judges concurring in the judgment alone. *See id.* at 1462-81, 46 U.S.P.Q.2d (BNA) at 1179-97; *see also Markman*, 517 U.S. at 389, 38 U.S.P.Q.2d (BNA) at 1470 (noting that patent claims have become increasingly technical due to legal doctrines that have evolved regarding the scope and form of claims).

47. *See, e.g.*, *Enzo Biochem, Inc.*, 188 F.3d at 1374.

48. A receptor is a site in a cell, often on a membrane, that can combine with another specific type of molecule to alter the cell's function. *See generally*, John C. Brown, *What the Heck is a Receptor?* (Jan. 1999) (describing receptors and their functions in layman's terms), *at* http://people.ku.edu/~jbrown/receptor.

49. *See Report of the National Institute of Health (NIH) Working Group on Research Tools* (June 4, 1998) (noting the use of reagents as research tools), *available at* http://www.nih.gov/news/researchtools/index.htm.

50. *See id.* (explaining that a firm that has identified a molecule like a receptor is likely to regard the molecule as an important proprietary discovery).

51. *See id.* (recognizing that many biotechnology firms see drug targets and assays developed from new molecules, rather than the molecules themselves, as "end products").

inventions that result from using the original invention.[52] In the latter situation, it would be more difficult for the upstream researcher to dominate the subsequent work of downstream investigators.[53]

Because of the risks and potential rewards, biotechnology and pharmaceutical companies have recognized the desirability of staking out an intellectual property position where they truly have exclusivity.[54] A greater degree of upstream protection implies greater control over, and reward from, later developments and downstream technologies.[55] It is not uncommon for parties to enter into contracts and licensing agreements such as material transfer agreements (MTAs)[56] or reach-through license agreements (RTLAs)[57] that include royalty and/or product reach-through terms. For example, an agreement might specify that the supplier of a new receptor will provide the receptor to a researcher for use in seeking new hormones so long as the supplier receives reach-through royalties on any new hormone discovered or invented by the researcher.[58]

In view of the high stakes involved, an increasing number of patent applicants seek protection for future downstream inventions through the patent statutes by way of "reach-through claims."[59] Such patent

52. *See id.* (describing the conflicts between government research organizations, public and private universities, and private firms over the licensing of new research tools in the context of biomedical research).

53. *See id.* (citing, for example, the fears of private firms that universities using private research tools might then license their independent discoveries to competitors of the private firms providing the tools).

54. *See, e.g.*, *Strategic Alliances: Leveraging the Tools of Drug Discovery*, *in* CONVERGENCE, *supra* note 2, at 48 (noting an increasing emphasis on achieving a later stage of product development prior to partnering, while retaining greater rights to the value of the end product).

55. *See, e.g.*, Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patent and Antitrust*, 16 BERKELEY TECH. L.J. 813, 833 (2001) (explaining that an original innovator has a strategic advantage over a person improving on the original innovation because of the ability of the original innovator to block the improver's secondary patent).

56. *See, e.g.*, Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 111 (1999) (noting that "many MTAs require researchers to assign or license intellectual property rights to discoveries made in the course of using the research tools").

57. *See, e.g.*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, SCI., May 1, 1998, at 698-99 (discussing the reach-through license agreement as a mechanism for licensing patents on upstream biomedical research); *see also* Nicky Androsov, *How Far Should Biotech Patents Extend?*, CURRENT DRUG DISCOVERY, Mar. 2001, at 33 (noting the increased prevalence of reach-through licenses for research tools), *available at* http://www.currentdrugdiscovery.com/CDDPDF/ANDROSOV.pdf.

58. *See* M. Marchione, *Foundation Amends Stem Cell Suit*, MILWAUKEE J. SENTINEL, Sept. 25, 2001, at 1G (chronicling a dispute between the parties of one such agreement concerning stem cell research).

59. "Reach-through claim" in the sense it is used here means a claim to a future

protection, if held valid, would avoid the need to negotiate reach-through rights.[60] They would greatly strengthen the patentee's dominance over future discoveries because such patents grant exclusive rights to the original patent owner by operation of law rather than as a result of negotiation.[61] While some in the patent field remain skeptical about the survivability of reach-through claims, many patent practitioners in the biotechnology arts are now waking up to the implications of protecting future inventions through this technique.[62] This phenomenon is growing on a global scale.[63]

III. FUNDAMENTAL LEGAL FRAMEWORK FOR TREATMENT OF REACH-THROUGH PATENT CLAIMS

In this article, the authors approach the question of the patentability of reach-through claims by applying the statutory requirements for utility,[64] written description,[65] and enablement.[66] The purpose of this article is to proffer a map of the geography of the legal terrain facing those seeking to patent reach-through claims. The article defines the requirements that need to be met and suggests how to meet those requirements. It explores the obstacles one must face and explains the patentability criteria that must be

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invention based on a currently disclosed invention.

60. *See Patenting Research Tools*, *supra* note 37 (noting the limited success of reach-through royalty licensing).

61. *See* Peter Steele, *'Mainly on Patents'—an Adventure in Reach-Through*, CURRENT DRUG DISCOVERY, Mar. 2001, at 36-37 (noting that it is easiest to demand royalties for access to both non-commercial technology and sales of the ultimate products discovered using that technology, if the patent itself has reach-through claims), *available at* http://www.currentdrugdiscovery.com/CDDPDF/STEELE.pdf.

62. *See id.* at 37 (noting the increasing use of reach-through claims in applications); *see also Trilateral Project B3b, Mutual Understanding in Search and Examination, Report on Comparative Study on Biotechnology Patent Practices, Theme: Comparative Study on "Reach-Through Claims"* 1 (Nov. 2001) [hereinafter *Trilateral Reach-Through Comparative Study*], *available at* http://www.uspto.gov/web/tws/B3b_reachthrough.pdf.

63. *See Trilateral Reach-Through Comparative Study*, *supra* note 62 (explaining a need among the USPTO, Japan Patent Office, and European Patent Office to reach a mutual understanding concerning the examination of reach-through claims in light of the trend toward such claims).

64. 35 U.S.C. § 101 (2001) ("Whoever 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 therefor, subject to the conditions and requirements of this title.").

65. *Id.* § 112, ¶ 1 ("The specification shall contain a written description of the invention, and of the manner and process of making and using it . . . ").

66. *Id.* ("The specification 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 connected, to make and use the same . . . ").

satisfied through the mechanism of a case study.

A. Case Study

Determining compliance with the statutory requirements for patentability cannot be accomplished by applying *per se* rules. It is always done on a case-by-case basis.[67] Thus, a case study approach is used to illustrate the legal principles. To begin, consider the following fact pattern in a patent application.[68]

B. Specification and Evidence of Record

An investigator identified the sequences of the bulk of cDNAs (complementary DNA) characteristic of mRNAs (messenger RNA) within a liver cell.[69] These sequences were collected in a computer database and compared to sequences known in the prior art. Based upon this homology analysis, the investigator determined that a selected novel cDNA sequence (SEQ ID NO: 1) is a member of an art-recognized family of R-receptors.[70] Neither evidence in the specification nor in the prior art raises doubts that the cDNA of SEQ ID NO: 1 is a member of the family of R-receptors.

In discussing the function and utility of the receptor, the patent application teaches that different R-receptors are important in a wide variety of distinct physiological processes. However, no particular biological or biochemical process in which the claimed new R-receptor is involved is disclosed. The specification does teach that activation of the claimed receptor induces a cascade of second-

67. *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40, 41 U.S.P.Q.2d (BNA) 1865, 1875 (1997) (expecting that the Federal Circuit will refine its formulation of legal tests on a case-by-case basis); Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323, 56 U.S.P.Q.2d (BNA) 1481, 1483 (Fed. Cir. 2000) (explaining that the test for whether the written description requirement has been met must be assessed on a case-by-case basis).

68. This case study is based on Example 3 of the *Trilateral Reach-Through Comparative Study*, *supra* note 62, at 31-37.

69. *See generally* Amgen, Inc. v. Chugai Pharm. Co. Ltd., 927 F.2d 1200, 1207-08 n.4, 18 U.S.P.Q.2d (BNA) 1016, 1022 n.4 (Fed. Cir. 1991); *In re O'Farrell*, 853 F.2d 894, 895-99, 7 U.S.P.Q.2d (BNA) 1673, 1674-77 (Fed. Cir. 1988) (providing a discussion of recombinant DNA technology).

70. It is beyond the scope of this paper to provide a discussion of when sequence homology is sufficient to assign a polynucleotide or polypeptide to a particular class of compounds. For more discussion of the issue, see *Trilateral Project B3b, Mutual Understanding in Search and Examination, Comparative Study on Biotechnology Patent Practices, Theme: Nucleic Acid Molecule-Related Inventions Whose Functions are Inferred Based on Homology Search* (Nov. 2001) [hereinafter *Trilateral Nucleic Acid Homology Comparative Study*], *available at* http://www.uspto.gov/web/tws/sr-3-b3b_bio_search.htm.

messenger signals, similar to that of a G-protein coupled receptor.[71] The specification also specifically describes a method of identifying or screening for agonists, i.e., compounds that activate the claimed receptor, wherein the activated state is detected when a cascade of second-messenger signals occurs. Thus, there is no reason to doubt that one could use the claimed R-receptor to find agonist activating compounds.[72] In addition, the application discloses three working examples wherein compounds activating the claimed receptor, namely compounds X, Y, and Z, were identified using the disclosed screening procedure. The application does not provide any structural information for compounds other than X, Y, or Z or methods of making compounds other than X, Y, or Z. Compounds X, Y, and Z do not share any common structure. Finally, although the claimed R-receptor was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

C. Claimed Inventions

Claim 1. An isolated and purified receptor, the sequence of which consists of SEQ ID NO: 1.

Claim 2. A method of identifying an agonist of the receptor of claim 1 comprising:

(a) preparing a candidate compound,

(b) contacting a cell which expresses said receptor on its surface with said candidate compound, and

(c) determining whether said candidate compound activates the receptor of claim 1, wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

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71. G protein-coupled receptors (GPCRs) are members of a superfamily of receptors which consist of a single protein chain that crosses a cell membrane seven times. Andrew D. Howard et al., *Orphan G-Protein-Coupled Receptors and Natural Ligand Discovery*, 22 TRENDS IN PHARMACOLOGICAL SCI. 132 (2001). GPCRs respond to stimuli as diverse as odorants, light, hormones, and neurotransmitters that selectively activate intracellular signaling events. Because GPCRs are centrally positioned in the cell membrane to initiate a cascade of cellular responses by diverse extracellular stimuli, it is unsurprising that modulation of GPCR function has resulted in the production of many marketable therapeutic agents. *See id.* Research indicates that GPCRs without natural activating ligands ("orphan GPCRs") may lead to significant discovery of important new cellular agents. As a result, the process of identifying ligands or 'de-orphanizing' these novel proteins is a growing field and fosters ongoing, exciting research in human physiology and pharmacology. *See id.*

72. For an overview of the approach to drug discovery exemplified herein, involving the identification and characterization of orphan receptors, see Shelagh Wilson et al., *Orphan G-Protein-Coupled Receptors: The Next Generation of Drug Targets?*, 125 BRIT. J. PHARMACOLOGY 1387 (1998).

Claim 3. An isolated and purified receptor agonist identified by the method of claim 2.

Claim 4. A method for the treatment of disease treatable by the agonist of claim 3, comprising administering to a host in need thereof a therapeutically effective amount of the agonist of claim 3.

Claim 5. A method for treating a disease treatable by compound X comprising administering to a host in need thereof a therapeutically effective amount of compound X.

Claim 6. A monoclonal antibody that recognizes the receptor of claim 1.

IV. LEGAL BACKGROUND

A. Statutory Background

To be granted a patent, at least the following criteria must be met: subject matter eligibility and utility (35 U.S.C. § 101), written description (35 U.S.C. § 112, ¶ 1), enablement (35 U.S.C. § 112, ¶ 1), clarity (35 U.S.C. § 112, ¶ 2), novelty and no loss of rights (35 U.S.C. § 102), and non-obviousness (35 U.S.C. § 103). For those applicants seeking to protect reach-through claims, issues pertaining to lack of utility, enablement, and written description are most likely to arise.[73] Satisfying these criteria may be the greatest challenge for such applicants.

1. Utility

For a subject to be patent eligible, it must be new and useful, and be encompassed within one of four expansive categories of invention.[74] As recited in 35 U.S.C. § 101: "Whoever 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 therefor, subject to the conditions and

73. *See, e.g.*, *Trilateral Reach-Through Comparative Study*, *supra* note 62, at 1 (analyzing the Industrial Applicability/Utility (35 U.S.C. § 101 (2001)) and Enablement/Support/Sufficiency/Written Description and Clarity (35 U.S.C. § 112) requirements); *see also* Rai, *supra* note 55, at 840 (noting the USPTO's balanced position on the utility requirement and the Federal Circuit's rigorous interpretation of the written description and enablement doctrines in the context of biotechnology).

74. *See* Diamond v. Chakrabarty, 447 U.S. 303, 309, 206 U.S.P.Q. (BNA) 193, 197 (1980) (asserting that Congress intended § 101 to "include anything under the sun that is made by man"); State Street Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373, 47 U.S.P.Q.2d (BNA) 1596, 1600 (Fed. Cir. 1998) (reasoning that Congress' repeated use of the term "any" in § 101 indicates its expansive understanding of permissible subject matter).

requirements of this title." It is not necessary, however, to dwell on what category a claimed invention might be pigeon-holed in because the Federal Circuit has instructed that the primary focus of inquiry lies not into which category an invention may fall, but rather on whether the claimed invention has practical utility.[75]

The statutory requirement that the invention be "useful"[76] has been interpreted as requiring that a specific and substantial credible utility, i.e., a practical utility, be available as of the filing date, either as asserted in the specification or as well established in the art.[77]

A "specific utility" refers to the particular claimed subject matter, unlike a *general* utility, which covers a broad or collective class of inventions.[78] One must distinguish between applications defining an invention's specific use and those indicating an ambiguous or unsubstantiated potential use.[79] For example, a general statement that a compound has "useful biological" properties and might aid in the treatment of some unnamed disorders is too vague to qualify as a specific utility.[80] A "substantial utility" should define a "real world"

75. *See State Street Bank*, 149 F.3d at 1375, 47 U.S.P.Q.2d (BNA) at 1602 ("The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to . . . but rather on the essential characteristics of the subject matter, in particular, its practical utility.").

76. Courts have recognized that the term "useful" applied with reference to the utility requirement can be a difficult term to define. *See* Brenner v. Manson, 383 U.S. 519, 529, 148 U.S.P.Q. (BNA) 689, 693 (Fed. Cir. 1966) (suggesting that a simple everyday word like "useful" can be "pregnant with ambiguity when applied to the facts of life").

77. *See id.* at 534-35, 148 U.S.P.Q. (BNA) at 695 (stating that the utility requirement is not satisfied "unless and until . . .a specific benefit exists in currently available form"); *In re* Ziegler, 992 F.2d 1197, 1203, 26 U.S.P.Q.2d (BNA) 1600, 1605 (Fed. Cir. 1993) (explaining that the potential role of an object cannot satisfy the utility requirement); *see also* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001) (recommending that patent applications should be rejected based on lack of utility if a person of ordinary skill in the art would not consider the asserted utility specific, substantial, and credible based on all the evidence in the record).

78. *See, e.g.*, U.S. Patent and Trademark Office, MANUAL OF PATENT EXAMINING PROCEDURE § 2107.01 (8th ed. Aug. 2001) [hereinafter MPEP] (contrasting specific and general utility), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep.htm.

79. *See id.* (explaining that applicants must show why and how the invention is considered useful, not that it may be useful in an unspecified context).

80. *See id.* (asserting that a general diagnostic utility is insufficient absent an indication of the specific condition to be diagnosed); *see also* Kawai v. Metlesics, 480 F.2d 880, 890, 178 U.S.P.Q. (BNA) 158, 165 (C.C.P.A. 1973) (contrasting the description of an invention as an anticonvulsant, which did suggest specific utility, with the general suggestion of "pharmacological effects on the central nervous system" which did not); *Application of Kirk*, 376 F.2d 936, 941, 153 U.S.P.Q. (BNA) 48, 52 (C.C.P.A. 1967) (holding that an indication that a compound is "biologically active" or has "biological properties" is insufficient to establish utility); *Application of Joly*, 376 F.2d 906, 907-08, 153 U.S.P.Q. (BNA) 45, 46-47 (C.C.P.A. 1967) (explaining

use.[81] If a real world context for using the invention is not reasonably apparent from the record, then the asserted utility is not substantial.[82]

It is inappropriate to label certain types of inventions as incapable of having a specific and substantial utility based solely on the setting in which the invention is used, for example, inventions used in a research or laboratory setting.[83] Many research tools used in laboratory analysis and the assessment of compounds, such as gas chromatographs, screening assays, and nucleotide sequencing techniques, have a clear, specific, and substantial utility in a research or intermediate context. However this evaluation alone does not focus on the invention's overall utility in a patent sense.[84] Instead, it is necessary to distinguish between inventions identifying a present and specific substantial utility from those requiring additional or future research to establish or verify usefulness.[85] In this process, applicants' use of labels like "research tool," "intermediate," or "for research purposes" are not determinative of whether the claimed invention has a specific, substantial and credible utility.[86]

These principles are now applied to the case study, starting with an analysis of claim 1, set forth *supra*. The fact pattern indicates that the claimed receptor is a member of the R-receptor family of proteins. However, assignment to a family of proteins is generally insufficient to meet the utility requirement unless such assignment would allow an artisan to assign a specific and substantial use to the new member of the protein family.[87] In this case, the claimed receptor does not

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that the mere disclosure that a compound may lead to the production of future compounds is insufficient to establish utility).

81. *See* MPEP, *supra* note 78, § 2107.01 (explaining the importance of a real world use).

82. *See id.* (providing examples of products that require further research and hence do not constitute substantial utilities); *see, e.g.*, *Brenner*, 383 U.S. at 534-35, 148 U.S.P.Q. (BNA) at 695 (reasoning that the basic quid pro quo underlying the patent monopoly requires that the invention be useful in its currently available form).

83. *See* MPEP, *supra* note 78, § 2107.01 (resolving the confusion that surrounds the patentability of research tools).

84. *See id.*; *see also* WORKING GROUP ON RESEARCH TOOLS, NAT'L INST. OF HEALTH, Background: Report of the National Institutes of Health (NIH) (June 4, 1998) (acknowledging the various perspectives on research tools and listing examples of such tools), *available at* http://www.nih.gov/news/researchtools/index.htm.

85. *See* MPEP, *supra* note 78, § 2107.01.

86. *See id.*; *see also Patenting Research Tools*, *supra* note 37 (explaining that the phrase "research tool" is not a term of art in the field of patent law, nor is there any legal significance in characterizing an invention as a research tool).

87. *See generally Trilateral Nucleic Acid Homology Comparative Study*, *supra* note 70 (providing a detailed analysis of the information necessary to satisfy the utility requirement on the basis of assignment to a family of proteins). Unless each member of the protein family has the same specific, substantial, and credible utility, one skilled in the art cannot predict *a priori* the function of the claimed protein. *See*

have a specific utility because the specification does not assert that the claimed R-receptor has any particular activity nor (on these facts) would one be readily apparent to a person skilled in the art. Furthermore, the claimed R-receptor does not have a substantial utility because further research is necessary to identify the specific use for the claimed R-receptor. Thus, claim 1 fails to comply with the utility requirement.

Similarly, claims 2-6, as recited *supra*, fail to comply with the utility requirement. Each of the aforementioned claims represents a prophetic invention downstream from the receptor. If the receptor does not have a specific, substantial, and credible utility, neither can any one of the methods of identifying an agonist of the receptor, an agonist of the receptor, a method of treating a disease treatable by an agonist of the receptor (where the specific disease to be treated is not disclosed), or a monoclonal antibody that recognizes the receptor.

It may be possible to overcome a rejection of claims 1-6 for failure to comply with the utility requirement by presenting objective evidence that supports the position that one of ordinary skill in the art would have recognized that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity, or that a specific and substantial purpose for agonizing such function was known to those of skill in the art.[88]

Alternatively, assume that the fact pattern is changed as follows. The specification also discloses that the receptor is useful for the diagnosis of obesity. The relationship between the absence of this receptor and the occurrence of obesity is determined by experimental measures of receptor activity, and there is no reason to doubt that the activation of this receptor can treat or inhibit obesity. In this situation, claim 1 would meet the utility requirement because use in diagnostic methods pertaining to obesity is a specific, substantial, and credible utility. Similarly, methods of identifying an agonist, the agonist itself, the method of treating obesity with the agonist, and the monoclonal antibody that recognizes the receptor would comply with the utility requirement.

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id.

88. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001) (discussing the importance of a person of ordinary skill in the relevant art appreciating the usefulness of the invention).

2. Requirements for the specification of a patent application

The specification of a patent application must meet the requirements set forth in 35 U.S.C. § 112, ¶ 1, which reads:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, 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 connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

This paragraph contains three requirements, usually denominated as: (1) written description, (2) enablement, and (3) best mode.

3. Written description

The purpose of the written description requirement is to ensure that a patent applicant has conveyed to those of skill in the art that the applicant possessed the invention at the time of filing the patent application.[89] The written description requirement of 35 U.S.C. § 112, ¶ 1, requires that a patent application describe the invention in such detail that one skilled in the art might reasonably determine that the inventor possessed the invention.[90] The inventor should describe the invention's identifying characteristics to fully define and distinguish the invention.[91] One may demonstrate possession in any of a variety of ways.[92]

In the case of chemical compounds, an applicant must disclose sufficient identifying characteristics such that those of skill in the art

89. *See* Vas-Cath v. Mahurkar, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d (BNA) 1111, 1117 (Fed. Cir. 1991) (suggesting that the written description serves to do more than simply explain how to make and use the invention). *Compare* Enzo Biochem, Inc. v. Gen-Probe, Inc., 285 F.3d 1013, 1021, 62 U.S.P.Q.2d (BNA) 1289, 1297, (Fed. Cir. 2002) (explaining that possession is a necessary, but not sufficient, condition to satisfy the written description requirement; applicant must also describe what is possessed).

90. *See* Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1014 (Jan. 5, 2001) [hereinafter Written Description Guidelines].

91. *See id.* (adding that the applicant should employ such descriptive means as words, structures, figures, diagrams, and formulas to accomplish this); *see also* Application of Wertheim, 541 F.2d 257, 262, 191 U.S.P.Q. (BNA) 90, 96 (C.C.P.A. 1976) ("The primary consideration is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure.").

92. *See* Written Description Guidelines, *supra* note 90 (listing possible ways to show possession including: demonstrating a reduction to practice, showing the invention was complete and ready for patenting, and describing the invention in sufficient detail).

can recognize that the applicant possessed the compound.[93] When the name of a compound, or an invocation of the compound's function, is insufficient to identify the compound, further description is needed.[94] Such disclosure might include descriptions of the structure, disclosure of the physical and/or chemical properties, the means of making the invention, and functional characteristics.[95] Functional characteristics may be disclosed by themselves or with some description of the correlation between the structure and function.[96] For example, if a strong correlation between structure and function has been accepted in a field of art, one skilled in that art would be able to confidently predict the invention's structure from a detailed description of its function.[97] If there is an accepted correlation between structure and function, the written description requirement may be satisfied through disclosure of function and minimal structure.[98] In the absence of such a correlation, an invention's structure likely will not be inferred from a mere recitation of function and minimal structure.[99] Without a well-established correlation, disclosure of function alone is little more than a hunting license and fails to meet the written description requirement.[100]

93. *See, e.g.*, Fiers v. Revel, 984 F.2d 1164, 1170, 25 U.S.P.Q.2d (BNA) 1601, 1606 (Fed. Cir. 1993) (applying the test of demonstrating possession to a dispute involving the DNA sequence encoding a protein).

94. For a biomolecule, such as a nucleic acid or a protein, a purely functional description may be inadequate. *See id.* ("Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived."); *see also* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 U.S.P.Q.2d (BNA) 1398, 1406 (Fed. Cir. 1997) (asserting, in the context of genes, that a definition by function indicates what the invention does, not what it is, and so does not satisfy the written description requirement); Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206, 18 U.S.P.Q.2d (BNA) 1016, 1021 (Fed. Cir. 1991) (stating that it is insufficient to define a chemical compound solely by its principal biological property, because without further specificity, that is merely "a wish to know the identity of any material with that biological property").

95. *See* Written Description Guidelines, *supra* note 90, at 1106 (listing factors to be considered in applying the written description test).

96. *See id.*

97. *See id.* at 1110 n.49; *see also* Purdue Pharma L.P. v. Faulding, Inc., 230 F.3d 1320, 1323, 56 U.S.P.Q.2d (BNA) 1481, 1483 (Fed. Cir. 2000) (requiring that "one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims").

98. *See* Written Description Guidelines, *supra* note 90, at 1110 n.49.

99. *See id.*

100. *See id.*; *see also* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 U.S.P.Q.2d (BNA) 1398, 1406 (Fed. Cir. 1997) (asserting that the written description requirement is not satisfied by merely providing "a result that one might achieve if one made that invention"); *In re* Wilder, 736 F.2d 1516, 1521, 222 U.S.P.Q.(BNA) 369, 372-73 (Fed. Cir. 1984) (affirming a rejection for lack of written description where the specification merely outlined the goals the inventors sought to

Applying these principles to the case study, it is apparent that claim 1, directed to an isolated and purified receptor whose sequence is specifically identified, complies with the written description requirement.[101] The scope of the claim is limited to a protein molecule whose primary structure is specifically disclosed.

Claim 2 is directed to a method of identifying agonist compounds. The specification teaches and exemplifies methods of screening for compounds that activate the claimed receptor. That is, the activated state can be detected when a cascade of second-messenger signals occurs. Based on these facts, one skilled in the art would recognize that the inventor possessed the claimed method since the specific steps are disclosed.[102]

Claim 3 encompasses agonists identified by the method of claim 2.[103] The claimed invention is drawn to a genus of agonist(s) identified by the method of claim 2 and the specification discloses three specific compounds within the scope of what is claimed. However, there is no evidence that there is any recognized structure/function relationship between the disclosed agonist compounds and any others that might be found using the claimed method.[104] Structural identifying characteristics of the genus members are not disclosed, nor is there a description of other identifying characteristics sufficient to describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan

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achieve). *But see* Fonar Corp. v. Gen. Elec., Co., 107 F.3d 1543, 1549, 41 U.S.P.Q.2d (BNA) 1801, 1805 (Fed. Cir. 1997) (finding, in the context of software, that disclosure of the function was adequate in that art).

101. The recitation of the complete amino acid sequence provides the entire description of the protein's primary structure. *See, e.g.*, Fiers v. Revel, 984 F.2d 1164, 1172, 25 U.S.P.Q.2d (BNA) 1601, 1607 (Fed. Cir. 1993) (holding that an application that sets forth a DNA's "complete and correct nucleotide sequence" meets the description requirement).

102. *See In re* Alton, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d (BNA) 1578, 1584 (Fed. Cir. 1996) (noting that the artisan may reasonably conclude that the inventor possessed the invention, even if the specification does not explicitly set forth every nuance of the claims).

103. Claim 2 is drawn to a process of identifying compounds, but it does not provide patent protection for compounds identified by the process. "A claim covers and secures a process, a machine, a manufacture, a composition of matter, or a design, but never the function or result of either, nor the scientific explanation of their operation." Markman v. Westview Instruments, Inc., 517 U.S. 370, 373, 38 U.S.P.Q.2d (BNA) 1461, 1463 (1996), quoting 6 Lipscomb 21:17, at 315-16 (emphasis added). Thus, even if claim 2 passed the statutory requirements, claim 3 must be examined for its own support in the disclosure as well as for novelty and nonobviousness.

104. *See Regents of the Univ. of Cal.*, 119 F.3d at 1568, 43 U.S.P.Q.2d (BNA) at 1406 (noting that a definition by function does not satisfy the written description requirement).

would recognize that the applicant was in possession of the claimed invention. Therefore, no written description supports the claimed invention.

This rejection of claim 3 might be overcome by showing objective evidence that supports the proposition that the particularly disclosed receptor agonists were representative of the structure of the group of molecules that would be detected or identified by the claimed method.[105]

Claim 4, directed to a method for the treatment of disease treatable by an agonist of the receptor of claim 1, fails to comply with the written description requirement for the same reasons set forth with respect to claim 3. Furthermore, the method encompasses treatment of an unspecified disease, and no evidence indicates that a treatable disease was known to the applicant. Thus, there is no disclosure of the actual process steps to be performed when implementing the invention in the real world. Based upon this fact pattern, one would conclude that the inventor did not possess the claimed method of use. In the absence of some understanding of the disease to be treated, which, if any, agonists could be used to treat said disease, and how such treatment would be performed, the artisan would not have accepted that the applicant was in possession of the claimed method.

Claim 5 fails to meet the written description requirement of 35 U.S.C. § 112, ¶ 1, for the same reasons as set forth above in the analysis of claim 4, except that compound X itself is adequately described.

Claim 6 satisfies the written description requirement. The scope of the claim is limited to an antibody that binds to a particularly recited protein. In view of the manner in which antibodies are made,[106] it is generally expected that if one is in possession of any particular protein, one would also have been "in possession," in the sense

105. *See* Amgen v. Chugai, 927 F.2d 1200, 1213, 18 U.S.P.Q.2d (BNA) 1016, 1027 (Fed. Cir. 1991) (explaining that an applicant may claim an invention by generically providing that the description satisfies § 112).

106. *See* Ailsa M. Campbell, MONOCLONAL ANTIBODY TECHNOLOGY PRODUCTION AND CHARACTERIZATION OF RODENT AND HUMAN HYBRIDOMAS IN LABORATORY TECHNIQUES at 86 (1985) ("In theory, the immune system of any animal is potentially totipotent. With a broad enough screening system it should be possible to detect antibodies to any antigen which has the potential to elicit a response."); *see also In re* Wands, 858 F.2d 731, 740, 8 U.S.P.Q.2d (BNA) 1400, 1406 (Fed. Cir. 1988) (reasoning that those skilled in the monoclonal antibody art could, using the state of the art and applicant's written disclosures, produce and screen other hybridomas secreting other monoclonal antibodies falling within the generic class without undue experimentation).

required by the patent law, of the corresponding antibody.[107] Compliance with the written description requirement does not require actual reduction to practice of the claimed invention.

4. Enablement

The enablement requirement appears in 35 U.S.C. § 112, ¶ 1 and requires that the applicant's specification provide sufficient disclosure about the invention.[108] A patent specification that provides only a starting point or direction for further research is not enabling because it does not provide full and clear terms that teach others how to make and to use an invention that will be discovered sometime in the future.[109]

As a general principle, the specification must provide enough instruction so that a person of ordinary skill in the art or technology would not have to exercise "undue experimentation" to make and to use the invention.[110] Factors that are usually considered in deciding whether a specification is sufficient include:

> (1) The quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

107. The Federal Circuit has not addressed this question directly. *See* Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1361, 47 U.S.P.Q.2d (BNA) 1705, 1719 (Fed. Cir. 1998) (relying on Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 43 U.S.P.Q.2d (BNA) 1398 (Fed. Cir. 1997), CellPro asserted that claims to an antibody were invalid under the written description requirement. The court found that Cellpro had not raised the issue below and thus declined to address it de novo on appeal).

108. 35 U.S.C. § 112 (2001) (mandating that the written description contain "the manner and process of making and using it, 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 connected, to make and use the same").

109. *See* Genentech, Inc. v. Novo Nordisk, 108 F.3d 1361, 1366, 42 U.S.P.Q.2d (BNA) 1001, 1005 (Fed. Cir. 1997) (clarifying that the patent monopoly is given in exchange for enabling disclosure, "not for vague intimations of general ideas that may or may not be workable"); *see also* Brenner v. Manson, 383 U.S. 519, 536, 148 U.S.P.Q. (BNA) 689, 696 (1966) ("[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

110. *See* Enzo Biochem Inc. v. Calgene Inc., 188 F.3d 1362, 1371, 52 U.S.P.Q.2d (BNA) 1129, 1140 (Fed. Cir. 1999) (explaining that although the necessity of conducting a reasonable amount of experimentation in order to practice an invention does not negate compliance with the statutory requirement of specification, it is critical that the experimentation not be undue); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 U.S.P.Q.2d (BNA) 81, 94 (Fed. Cir. 1986) (stating that the enablement requirement is still satisfied with the necessity of experimentation, so long as the experimentation is not unduly extensive).

predictability or unpredictability of the art, and (8) the breadth of the claims.[111]

Applying these principles to the case study set forth above, it is apparent that claim 1, an isolated and purified receptor, complies with the "how to make" prong of 35 U.S.C. § 112, ¶ 1.[112] The disclosure of the critical sequence data needed is sufficient, as the applicant's disclosure "need not teach, and preferably omits, what is well-known in the art."[113] Given the primary protein sequence, the skilled artisan would have been able to prepare the claimed protein. However, this claim does *not* meet the requirement for the "how to use" prong of 35 U.S.C. § 112, ¶ 1, because the disclosure does not teach a use that would meet the utility requirement of 35 U.S.C. § 101.[114]

Claim 2 is directed to a method of identifying an agonist, or activating compound, of the receptor of claim 1. As a general rule, the extent of the patent right claimed must have a reasonable correlation with the extent of the enabled disclosure provided to the public.[115] In this case, the patent application specification includes a

111. *See Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d (BNA) at 1404; *see, e.g.*, *Enzo Biochem. Inc.*, 188 F.3d at 1370-75, 52 U.S.P.Q.2d (BNA) at 1135-39 (concluding, through use of the *Wands* factors, that the genetic antisense technology application did not meet the enablement requirement because it was too broad and encompassing, highly unpredictable, unable to be created by those skilled in antisense technology, and lacking in directions and working examples).

112. It is assumed that at the time the example application was filed, one of ordinary skill in the art, working with the sequence data provided by the applicant, could have synthesized the protein with the ordinary chemical means available at the time or could have expressed the protein using the genetic engineering means available at the time.

113. *Hybritech, Inc.*, 802 F.2d at 1384, 231 U.S.P.Q. (BNA) at 94. Courts imply that it is not necessary to explain every detail, since the inventor is speaking to persons of ordinary skill in the art. *See, e.g.*, *Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d (BNA) at 1404 (finding the deposit of living materials in cell depositories necessary and sufficient to satisfy the enablement requirement of the statute).

114. A strong correlation exists between the "how to use" prong of the enablement requirement in 35 U.S.C. § 112, ¶ 1 and the requirement for a disclosure of practical utility found in 35 U.S.C. § 101. *See* Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1358, 52 U.S.P.Q.2d (BNA) 1029, 1034-35 (Fed. Cir. 1999) ("If a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement."); *In re* Brana, 51 F.3d 1560, 1569, 34 U.S.P.Q.2d (BNA) 1437, 1443 (Fed. Cir. 1995) (classifying practical utility as an implicit requirement of the enablement provision); Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571, 24 U.S.P.Q.2d (BNA) 1401, 1412 (Fed. Cir. 1992) (clarifying that if the subject matter of a patent is inoperable, then the patent may fail to meet both the utility requirement and the enablement requirement).

115. *See In re* Fisher, 427 F.2d 833, 839, 166 U.S.P.Q. (BNA) 18, 24 (C.C.P.A 1970) (prescribing this correlation); *see, e.g.*, *In re* Vaeck, 947 F.2d 488, 495, 20 U.S.P.Q.2d (BNA) 1438, 1444 (Fed. Cir. 1991) (finding a lack of correlation between the narrow disclosure by appellants of certain cyanobacterial genera and the broad degree of

general description of a series of screening procedures commensurate in scope with those recited in the claims. Considering the level of skill and knowledge in the art, one skilled in the art would be able to practice the first two process steps of claim 2 (preparing a candidate compound and contacting a cell that expresses the receptor with the candidate compound) because the receptor is enabled. One skilled in the art would be able to practice the third step (determining whether the candidate compound activates the receptor) because the specification teaches that the activated state can be detected when a cascade of second-messenger signals occurs. Thus the claim meets the "how to make" prong of 35 U.S.C. § 112, ¶ 1. However, claim 2 fails to meet the "how to use" requirement of 35 U.S.C. § 112, ¶ 1, for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101.

Claim 3 is directed to an isolated and purified receptor agonist identified by the method of claim 2. The issue of extrapolating results from one compound to other more or less similar compounds arises frequently in pharmacology and biotechnology. Thus, courts generally decide on a case-by-case basis whether those of skill in the art would accept results obtained with tested compounds as sufficient to support an inference of activity for an untested compound.[116] In this case, the specification discloses three compounds that fall within the scope of the claim. However, the instructions do not detail how to make agonists other than X, Y, and Z. No factors indicate that X, Y, and Z are a representative number of structurally related compounds such that they constitute full, clear, and concise instructions for making other agonists. Courts generally require a full range of disclosure pertaining to the operation of the claim.[117]

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protection the appellants wanted to obtain for the gene expression of all cyanobacteria).

116. *See, e.g.*, Brenner v. Manson, 383 U.S. 519, 531-32, 148 U.S.P.Q. (BNA) 689, 694 (1966) (finding that, despite the reference in the respondent's application to an adjacent homologue, the respondent failed to present a sufficient likelihood that his process would result in a steroid with similar tumor-inhibiting characteristics); *see also Brana*, 51 F.3d at 1567, 34 U.S.P.Q.2d (BNA) at 1442 (noting that "evidence of success with structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility").

117. *See* PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 U.S.P.Q.2d (BNA) 1618, 1623 (Fed. Cir. 1996) ("In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim.").

One skilled in the art would not know the identity of any non-disclosed compound falling within the scope of the claim and consequently would not be able to make it. An assay for *finding* a product is not equivalent to a method for making that product.[118] Therefore, claim 3 fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, ¶ 1.

Similarly, and for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101, the claimed agonist fails to meet the requirements of the "how to use" prong of 35 U.S.C. § 112, ¶ 1.

Claim 4 is directed to treating a disease with an agonist of the receptor set forth in claim 1. As noted above, the enablement requirement mandates that the specification allows artisans to make and to use the invention without undue experimentation.[119] In the instant case, no treatable disease is disclosed in the specification, nor is there any information as to how any particular undisclosed agonist would have been administered to treat any specific disease. In view of these facts, the artisan would not have been able to make the claimed invention without undue experimentation. Similarly, and for reasons set forth above in the analysis of the compliance of the claimed

118. A claim to the process of claim 2 would not "cover" compounds identified by the process. *See* Markman v. Westview Instruments, Inc., 517 U.S. 370, 373, 38 U.S.P.Q.2d (BNA) 1461, 1463; *see also* Bayer AG v. Housey Pharm., Inc., 169 F. Supp. 2d 328, 330, 61 U.S.P.Q.2d (BNA) 1051, 1053 (D. Del. 2001) (holding that while it is an act of infringement to import into the United States, or offer to sell, sell, or use within the United States, a product which is made by a process patented in the United States pursuant to 35 U.S.C. § 271(g), that section "addresses only products derived from patented *manufacturing processes*, i.e., methods of actually making or creating a product as opposed to methods of gathering information about, or identifying, a substance worthy of further development")(emphasis in original). There are situations where a product composition can be defined by the process of making the compound. Where the transformation of an identified starting material is detailed in one or more process steps, a product-by-process claim can be appropriate for an otherwise patentable product that resists definition by other than the process by which it was made. *See, e.g., In re* Thorpe, 777 F.2d 695, 697, 227 U.S.P.Q. (BNA) 964, 965-66 (Fed. Cir. 1985) (explaining that novelty and nonobviousness of the product are not assured by the novelty or nonobviousness of the process). However, the process of claim 2 does not have any steps that produce a new product by transforming a starting material because claim 2 assays an existing compound without producing a new compound. The process of claim 2 is accurately described as a process that uses a starting material. *See* Mentor Corp. v. Coloplast, Inc., 998 F.2d 992, 997, 27 U.S.P.Q.2d (BNA) 1521, 1526 (Fed. Cir. 1993) (distinguishing product-by-process claims from process claims relating to how a product is used).

119. *See* Enzo Biochem Inc. v. Calgene Inc., 188 F.3d 1362, 1371, 52 U.S.P.Q.2d (BNA) 1129, 1140 (Fed. Cir. 1999); Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195, 49 U.S.P.Q.2d (BNA) 1671, 1676 (Fed. Cir. 1999) (discussing the enablement requirement).

invention with the requirements of 35 U.S.C. § 101, the claimed method fails to meet the requirements of the "how to use" prong of 35 U.S.C. § 112, ¶ 1.

Claim 5, directed to a method for treating a disease with a specific agonist compound, fails to meet the requirements of the enablement requirement of 35 U.S.C. § 112, ¶ 1, for the same reasons as set forth above in the analysis of claim 4, except that one skilled in the art would be able to make compound X based on the disclosure.

Claim 6 is directed to a monoclonal antibody that recognizes the receptor of claim 1. Courts generally find that with claims relating to chemical matter, generic formulae are sufficiently specific to provide adequate descriptions of the claimed creation.[120] In the instant case, given the primary protein structure from which an antibody is to be made, one skilled in the art would be able to use routine and well-known methods to prepare an antibody to such a target.[121] Therefore this claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, ¶ 1.

However, claim 6 does *not* meet the requirement for the "how to use" prong of 35 U.S.C. § 112, ¶ 1, because the disclosure does not teach a use that would meet the utility requirement of 35 U.S.C. § 101.

5. Best mode

The third requirement of 35 U.S.C. § 112, ¶ 1, is that the applicant's specification shall set forth the best mode contemplated by the inventor[122] for carrying out the claimed invention.[123] Determining compliance with the best mode requirement requires a

120. *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 U.S.P.Q.2d (BNA) 1398, 1406 (Fed. Cir. 1997) (explaining that with claims pertaining to chemical materials "generic formulae usually indicate with specificity what the generic claims encompass").

121. *See In re* Wands, 858 F.2d 731, 736, 8 U.S.P.Q.2d (BNA) 1400, 1403-04 (Fed. Cir. 1988) (discussing the relationship between antibodies and antigens).

122. *See* Eli Lilly & Co. v. Barr Labs. Inc., 251 F.3d 955, 963, 58 U.S.P.Q.2d (BNA) 1869, 1874 (Fed. Cir. 2001) (noting that the best mode requirement is part of the bargain for exchange contemplated in granting a patent right).

123. *See, e.g.*, *id.* at 966, 58 U.S.P.Q.2d (BNA) at 1877 (noting that the patentee need not disclose an "unclaimed preferred mode for accomplishing a routine detail . . . because one skilled in the art is aware of alternative means for accomplishing the routine detail that would still produce the best mode of the claimed invention"); N. Telecom Ltd. v. Samsung Elecs. Co., 215 F.3d 1281, 1288, 55 U.S.P.Q.2d (BNA) 1065, 1070 (Fed. Cir. 2000) (holding that the best mode requirement was satisfied even though thin-line etching, an unclaimed, preferred method for the process for gaseous etching of aluminum and aluminum oxides, was not disclosed in the specification because the claim sufficiently described a general process of plasma etching and the best mode for carrying out that process).

two-prong factual inquiry.[124] First, a fact-finder must decide whether an inventor had the best mode for practicing the claimed invention at the time the inventor filed the application.[125] To make this determination, the fact-finder must assess the inventor's state of mind at the time of filing.[126] Second, if the inventor did possess a best mode, the fact-finder must determine "whether the written description disclosed the best mode such that a person skilled in the art could practice it."[127] This determination requires an objective inquiry that focuses on the scope of the claimed invention and the level of skill in the art.[128] Courts will usually determine if the best mode requirement is satisfied based upon whether the applicant has contemplated and subsequently concealed the best mode by not disclosing it.[129] If a claim is truly a reach-through claim, the applicant may not have set forth any mode or embodiment of the invention because the discovery or invention has not been made yet. While this is not a best mode issue, it may be an enablement problem.[130]

V. IMPLICATIONS OF FAILURE TO COMPLY WITH 35 U.S.C. §§ 101 AND 112, ¶ 1

The inadequate disclosure problems detailed above could very well prove to be fatal to the claims in this case study. Applicants cannot amplify the description by adding later-discovered evidence because such efforts go beyond the specification as filed and are prohibited as introducing new matter.[131] New or amended claims that introduce elements or limitations that are not supported by the disclosure as it is originally filed violate the written description requirement.[132]

124. *See Barr Labs. Inc.*, 251 F.3d at 963, 58 U.S.P.Q.2d (BNA) at 1874 (setting forth the test).
125. *See id.*
126. *See id.*
127. *See id.*
128. *See id.*
129. *See* Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 927-28, 16 U.S.P.Q.2d (BNA) 1033, 1035 (Fed. Cir. 1990) (articulating the importance of concealment).
130. *See* Application of Glass, 492 F.2d 1228, 1233, 181 U.S.P.Q. (BNA) 31, 35 (C.C.P.A. 1974) (indicating that in at least some situations "[f]ailure to set forth any mode . . . equivalent to non-enablement").
131. *See* 35 U.S.C. § 132 (2001) (stating that "[n]o amendment shall introduce new matter into the disclosure of the invention"); *id.* § 251 (indicating that "[n]o new matter shall be introduced into the application for reissue" of a defective patent).
132. *See, e.g.*, Application of Lukach, 442 F.2d 967, 969, 169 U.S.P.Q. (BNA) 795, 796-97 (C.C.P.A. 1971) (determining that the generic disclosure and singular specific example provided by the previously-filed patent application did not support the subgenus range at issue); *see also* Application of Smith, 458 F.2d 1389, 1395, 173 U.S.P.Q. (BNA) 679, 683 (C.C.P.A. 1972) (concluding that a "subgenus is [not]

While the written description requirement of 35 U.S.C. § 112 does not mandate *in haec verba* disclosure,[133] it requires that newly added claim limitations must be supported in the specification through express,[134] implicit,[135] or inherent disclosure.[136]

Furthermore, it is doubtful that the applicant could overcome these defects through affidavit or declaration showings under 37 C.F.R. § 1.132.[137] After-the-fact submissions cannot make up for what is required to be in the specification by supplementing the as-filed application. Affidavits or declarations presented to show that the disclosure of an application is sufficient to one skilled in the art are not acceptable to establish facts that the specification itself should recite.[138] Each patent specification filed is required to disclose to the public how to use an invention. If necessary information is added in a later filed application that asserts benefit to an earlier application that is lacking such information, the later filed application is not entitled to the benefit of the filing date of the earlier filed application.[139] In some cases, breaks in the continuity of disclosure

necessarily described by a genus encompassing it and a species upon which it reads").

133. *See, e.g.*, Fujikawa v. Wattanasin, 93 F.3d 1559, 1570, 39 U.S.P.Q.2d (BNA) 1895, 1904 (Fed. Cir. 1996) (requiring only that the disclosure in the application "reasonably convey" to those skilled in the art that the inventor possessed the disputed subject matter).

134. When an explicit limitation in a claim "is not present in the written description whose benefit is sought, it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation." Hyatt v. Boone, 146 F.3d 1348, 1353, 47 U.S.P.Q.2d (BNA) 1128, 1131 (Fed. Cir. 1998).

135. *See, e.g.*, *Application of Smith*, 458 F.2d at 1395, 173 U.S.P.Q. (BNA) at 683 (noting the lack of an implicit relationship between a subgenus and encompassing genus).

136. "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *See In re* Robertson, 169 F.3d 743, 745, 49 U.S.P.Q.2d (BNA) 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* (citations omitted).

137. *See* 37 C.F.R. § 1.132 (2002) ("When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of oath or declaration under this section."); *see generally* MPEP, *supra* note 78, § 716 (providing a detailed discussion of affidavits and objections filed under 37 C.F.R. § 1.132).

138. *See In re* Buchner, 929 F.2d 660, 661, 18 U.S.P.Q.2d (BNA) 1331, 1332 (Fed. Cir. 1991) (finding the declaration by an expert as to how he would construct elements necessary to the claimed invention was insufficient either to make up for the fact that the construction did not appear in the application or the prior art, or to demonstrate that the construction was well-known to the relevant artisans).

139. *See, e.g.*, Application of Hogan, 559 F.2d 595, 609, 194 U.S.P.Q. (BNA) 527,

may permit application of intervening references that preclude patentability.[140]

CONCLUSION

When a new receptor is discovered, and its ligands, agonists, antagonists, or binding partners remain unknown, the receptor might be used in screening assays to discover the unknown ligands or to serve other functions. This is not unlike panning for gold. Just as the seller of a pan for use in panning for gold might like to have a claim to the gold discovered by operators using the pan, the inventor of a new receptor might like to have a claim to whatever ligands, agonists, antagonists or binding partners of the receptor that might be discoverable.[141] If a claim to such compounds is presented in an application in which the only information about the compounds is that they remain to be discovered, it is likely that the claim will be rejected for lack of an adequate written description and lack of an enabling disclosure.

Reach-through claims are not patentable because they do not satisfy the requisite disclosure criteria for obtaining a patent, which is found in the requirements of 35 U.S.C. §§ 101 and 112, ¶ 1. The reach-through invention does not exist as of the filing date of the application for patent. By its nature, the inventor cannot describe it in such terms that one skilled in the art would have recognized that the inventor had possession of the claimed subject matter, nor can the inventor provide sufficient teachings of how to make or use the reach-through invention. Indeed, the inventor cannot provide a sufficient disclosure so others may know what it is that they are excluded from making, using, selling, offering for sale, or importing into the United States.[142]

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540 (C.C.P.A. 1977) (determining that the failure to disclose a graph in a 1956 patent application that had been disclosed previously in a 1953 application and subsequently in the 1967 application created a gap in the continuity of disclosure necessary to secure the benefit of 35 U.S.C. § 120 and resulted in the claim receiving only the benefit of the 1967 filing date in which it was introduced).

140. *See id.* at 604, 194 U.S.P.Q. (BNA) at 536 (discussing the effect of intervening references).

141. Another commentator on reach-through claims captured the essence of these mechanisms by asking "if I sell you a piano, can I have a royalty on the songs you write?" Terry Stancliffe, Cantab Pharmaceuticals, *quoted in* Nicky Androsov, *How Far Should Biotech Patents Extend?*, CURRENT DRUG DISCOVERY, Mar. 2001, at 34, *available at* http://www.currentdrugdiscovery.com/CDDPDF/ANDROSOV.pdf.

142. Similarly, if an inventor is granted a patent that includes a reach-through claim, there is some probability that in an enforcement proceeding or infringement suit, the patent owner may find that, as a true appreciation of what the invention encompasses evolves, subject matter in the prior art will be found to invalidate the

Reach-through claims are inconsistent with the purpose of the patent statutes, which seek to implement ways to "promote the progress of . . . useful arts," because they could inhibit the progress of scientific development without compensating the public.[143] As gatekeeper for the patent system, the USPTO must take a conservative approach with respect to determining whether such claims meet the utility, written description, and enablement requirements.[144] Challenges by the adventuresome in the courts are expected. The law is dynamic and decisions of the federal courts and/or legislation enacted by Congress may change the future landscape and force a new respect for reach-through claims. Applicants seeking reach-through claims will either have to bear the burden of convincing the USPTO, and ultimately the courts, that such claims are consistent with the patent laws,[145] or bear the burden of convincing Congress that statutory changes permitting such claims are necessary to protect embryonic industries and to allow these industries to flourish and to deliver the promise of a better tomorrow.

claims under § 102. *See* 35 U.S.C. § 102 (2001) (setting forth the specification for novelty and the conditions that can lead to the loss of a patent).

143. *See* Brenner v. Manson, 383 U.S. 519, 534, 148 U.S.P.Q. (BNA) 689, 695 (1966) (noting this danger of blocking scientific development without compensation).

144. *See* Rai, *supra* note 55, at 841 (concluding that "[w]hile the PTO guidelines reflect the Federal Circuit's position, they also respond quite specifically to concerns lodged both by the National Institutes of Health and the academic research community about the problems for subsequent researchers created by broad patents on upstream research").

145. Prophetic disclosures in biotechnology inventions have generally received a hostile reception in the Federal Circuit. *See* Enzo Biochem. Inc. v. Calgene, Inc., 188 F.3d 1362, 1372, 52 U.S.P.Q.2d (BNA) 1129, 1136-37 (Fed. Cir. 1999) (finding that the high unpredictability in the antisense technology and the extensive nature of experiments to practice the technology rendered the disputed claims invalid); Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1567, 43 U.S.P.Q.2d (BNA) 1398, 1405 (Fed. Cir. 1997) (stating that a written disclosure must allow skilled experts to practice the invention or method and not just provide a "mere wish or plan" for practicing the invention in the future); Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206, 18 U.S.P.Q.2d (BNA) 1016, 1020-21 (Fed. Cir. 1991) (clarifying that the conception of an invention necessary for the disclosure required for patents entails then current possession of an operative method for making the invention).