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	Barbara Reres	(202) 344-4736
DATE:	CLIENT/MATTER NUMBER:	PAGES, EXCLUDING COVER:
9/15/2004		5

MESSAGE:

Mr. Latker:

Sorry for the miscommunication at my end. So glad you called to check on this.

Barbara Reres

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TELEFAX CONTROL SHEET

SENT TO: Howard Baeman

DATE SENT: 9/17/04

SUBJECT: Telephone Call

No. of pages (including this cover sheet): 6

FROM: Norm Latker

Remarks:

I. SUMMARY

The University of Rochester is the owner of U.S Patent Number 6,048,850 (the '850 patent), which claims methods of treating pain, inflammation and other diseases in humans by selectively inhibiting an enzyme known as Cox-2 over a different enzyme, Cox-1. The '850 patent describes the inventors' discovery of Cox-2, and their discovery that Cox-2 is linked to inflammation. The patent sets forth experiments showing that Cox-2 is inhibited by traditional non-steroidal anti-inflammatory drugs ("NSAIDs"), and that different NSAIDs inhibit Cox-2 to different degrees. The '850 patent shows that traditional NSAIDs also inhibit Cox-1, and that it is this inhibition of Cox-1 that leads to NSAIDs' side effects, like ulcers and bleeding. Finally, the '850 patent discloses tests that permit scientists to identify compounds that selectively inhibit Cox-2 – *i.e.*, inhibit Cox-2 much more than Cox-1.

In April of 2000, the University filed a lawsuit against Pfizer for infringement of the '850 patent; Pfizer manufactures selective Cox-2 inhibitors such as Celebrex®. On February 13, 2004, a panel of the United States Court of Appeals for the Federal Circuit ruled that the '850 patent is invalid for failure to meet the judicially-created "written description" requirement. Ignoring the sworn declarations of two experts in the field opining that the claimed method of treatment was sufficiently described to skilled scientists (the persons for whom patents are written), the panel held that because the '850 patent does not disclose the precise chemical formula of a compound useful in the claimed method the patent is invalid.

On July 2, 2004, a sharply divided Federal Circuit denied Rochester's petition for rehearing by the full court. The denial prompted 40 pages of opinions from the judges, including strong dissents. The dissenters, citing a schism in the Federal Circuit regarding the existence of, and standard for compliance with, the written description requirement, urged resolution by the full Federal Circuit or the United States Supreme Court. The University is now appealing to the United States Supreme Court.

If allowed to stand, the *Rochester* decision will constitute a fundamental shift in patent law. It changes the balance between protection of basic research and protection of commercial products, eviscerating the protections for the former and instituting a per se preference for the latter. The Federal Circuit decision--which is not limited to biotechnology, but is of general application--puts the determination of patent worthiness in the hands of judges and disregards the viewpoint of skilled scientists, placing a multitude of university patents at risk.

II. THE ROCHESTER DECISION WILL HAVE A NEGATIVE IMPACT ON UNIVERSITIES, RESEARCH INSTITUTIONS, INNOVATION, AND ECONOMIC GROWTH

A. U.S. Policy Supports Basic Research And Patent Protection In Order To Encourage Innovation And Technology Transfer

The rise of the American research university is without question one of the most important developments of the latter half of the twentieth century. Modern research universities grew out of the partnership between the federal government and universities fashioned in the

aftermath of World War II. Following the war, increased federal funding of research accompanied the creation of federal agencies dedicated to the support of science and technology, notably the National Science Foundation ("NSF"), the National Institutes of Health ("NIH") and the Department of Energy's Office of Science (the successor agency to the U.S. Atomic Energy Commission). The mission of these federal agencies has since evolved to focus on supporting research requiring a long timeline to commercialization.

The extraordinary success of this government-university partnership in stimulating and sustaining basic research enabled U.S. corporations to focus their in-house research on applied R&D with good prospects for near-term commercialization. This has benefited companies economically, but the arrangement can only advance long-term U.S. economic objectives if universities and corporations forge their own commercialization partnership.

The Bayh-Dole Act of 1980 was designed to foster such a partnership, and thereby stimulate U.S. innovation and bring new technologies to the public. It was recognized that innovative breakthroughs were frequently the product of federally-funded university research; although universities were well-suited to accomplish such basic research, private industry was best-suited to commercialize these new technologies. The goal of the Bayh-Dole Act was to effectuate the transfer of pioneering breakthroughs resulting from basic research to industry, which would commercialize the technology and bring new products to market.

The Bayh-Dole Act uses the patent system to achieve these goals. Under the Act, ownership of discoveries and inventions arising out of federally-funded research is vested in the institutions carrying out the research. Such institutions can obtain patents on newly-discovered technology, and exclusively license those patents to the private sector. The Act thus provides incentives to universities to patent and market their inventions, and incentives to industry (via exclusive rights to new technology) to invest in and commercialize early-stage technology.

The Bayh-Dole Act has sparked an unparalleled blossoming of innovation and economic growth. In 1980 there were only 25 universities engaged in technology transfer; there are now more than 200. Today, universities file thousands of patent applications and are awarded thousands of patents each year. Respondents to the annual survey carried out by the Association of University Technology Managers ("AUTM") reported that in 1999 alone, nearly 4,000 university licensing agreements were executed. In 2000 that number increased to 4,300, and in 2002 it exceeded 4,600. Since the passage of the Act, over 2,200 new companies and start-ups have been formed around federally-funded scientific inventions, and some 260,000 jobs have been created. Furthermore, between 1998 and 2002, over 2,000 new products resulting from academic research were made available to the public. Technology transfer activities are estimated to contribute about $40 billion annually to the U.S. economy.

B. The *Rochester* Decision Changes the Standard For The Patentability of Innovation

The *Rochester* decision marks a fundamental shift in the types of innovation that the law recognizes as patentable, and has far-reaching implications for the continued vitality of the Bayh-Dole paradigm. Previously, patentable inventions included those innovations that inventors had not put into practice, but had described in a way that permitted skilled scientists to make and use them with only routine effort. *Rochester* makes clear that, at least in the chemical arts (and

perhaps all arts), before an innovation can be patented, it must actually be made or practiced *by the inventors*.

Prior to *Rochester*, it was understood that a court assessing the adequacy of an invention's description must do so from the view point of skilled scientists in the field to which the invention pertains. This is - and should be- a very factual examination of the invention, the art, and the understanding and language of skilled scientists. Here, the University described its methods of treatment in the language of biochemists and molecular biologists -- the University described a novel drug target, its link to inflammation, demonstrated how to inhibit the target, and provided materials and instructions for identifying useful compounds. The University provided a groundbreaking blueprint that has been used again and again by the pharmaceutical industry. But instead of examining the University's disclosure in light of what someone skilled in the medical field would learn from it, the court ruled that the patent was facially invalid, because it failed to include the precise formula of a compound useful in the claimed methods. The court never asked whether such a chemical formula was needed by those scientists who practice the University's invention, and, more critically, ignored expert testimony that said such formulas were *not* needed. In effect, the court said that it was not enough for university scientists to discover a novel enzyme, describe its contribution to health and disease, teach the benefits to patients of drugs that would selectively inhibit this enzyme, and teach how to make a new generation of such drugs. Instead, the court ruled as a matter of law that university scientists must now develop and commercialize the drugs themselves.

The net result of the *Rochester* decision is a rule of patentability that undermines the policy foundations of the Bayh-Dole Act. The Bayh-Dole model uses the patent system to effectuate the transfer of early-stage technology to the public. The *Rochester* decision, however, eliminates the ability of universities and research institutions to obtain patents on early-stage technology founded upon basic research. This in turn eliminates the primary incentive for industry to invest in and undertake commercial development of basic inventions – the prospect of exclusive rights to the technology. Absent industry investment in new technologies resulting from university research, the Bayh-Dole paradigm breaks down.

C. The *Rochester* Decision Forces Universities To Engage In Costly, Inappropriate Commercial Development

The *Rochester* decision holds that in order to obtain a patent, universities must engage in commercial development far beyond that contemplated by Bayh-Dole. For example, biologists and doctors will continue to create essential, life saving inventions, and will describe those inventions in a way that permits scientists in industry to make and practice their inventions. The *Rochester* decision, however, denies such biologists and doctors patents – even though they may identify the cornerstone of their discipline -- until they undertake a drug discovery program. Under the Bayh-Dole paradigm, such an effort is within the province of private industry, which can most efficiently commercialize inventions. Requiring university laboratories to engage in such commercial development results in a break-down of the Bayh-Dole paradigm and frustrates the policies behind it.

Even if a university is able to secure a patent to early-stage technology founded on basic research, licensing the patent will prove difficult as those in industry who would normally seek a license will have little confidence that the patent would survive a validity challenge. Moreover,

following *Rochester*, industry giants will be emboldened to force universities to engage in costly court battles to defend the validity of patents founded upon basic research.

Whether (1) universities elect not to engage in commercial development, or (2) industry refuses to take a license to patents founded on basic research, universities will be deprived of a royalty stream stemming from basic inventions, a revenue stream upon which universities rely to fund additional research into new technologies.

D. The *Rochester* Decision Weakens the Tripartite Partnership Among the Federal Government, Universities, and Industry

While Bayh-Dole has proven successful at fueling technology transfer and reinforcing the tripartite partnership among the government, universities, and industry, this productive partnership and the Act itself is now being undermined by the increased cost of patenting university-owned intellectual property and the expense of defending the validity of these patents once they are issued.

Moreover, the *Rochester* decision impliedly favors the commercial partner over universities which engage in fundamental research. In so doing, the *Rochester* decision thus disrupts the balanced relationship between government, universities and industry, because it undercuts the interaction between public and private research which allows the public to receive the benefits of innovative science sooner.

But there is another danger as well. The rise of research universities has made advanced technical education in the U.S. the worldwide option of choice in science disciplines. The outcome has been beneficial both to the U.S., where many of these very talented scientists have emigrated after earning their degrees, and to the nations from which these students originated, since those who returned home jump-started national technical industries. However, the net result is win-win only if the U.S. continues to maintain the vitality of the government-university-industry partnership that has helped create the world's largest economy. Ill-considered decisions, such as the one reached in *Rochester*, have grave implications for American research.

Reres, Barbara A.

From: Drew Days [drew.days@yale.edu]
Sent: Monday, August 23, 2004 11:17 AM
To: Bayh, Birch
Subject: Fwd: Summary of UR and Bayh Dole_v1.DOC

Dear Senator Bayh:

I enjoyed very much our telephone conversation last week about the University of Rochester case. Thank you very much for taking my call. As I mentioned to you then, the University is preparing to file a petition for certiorari at the end of September seeking Supreme Court review of the Federal Circuit's recent unfavorable ruling. I think that an amicus brief from you (and Senator Dole, if possible) urging the Court to grant review, in light of the impact of the Circuit Court's decision on the research regime established by the Bayh -Dole Act, would be of great assistance to my client, the University, and to the Court. Such a brief would not necessarily have to take a position on the merits--although that would be most welcome-- but could merely help us convince the Supreme Court that the case is "cert-worthy." Such a brief would have to be filed toward the end of October. I have included, as promised, an attachment to this message that should give you a general sense of what the litigation is about and of the potential consequences of its resolution for Bayh-Dole. I also promised to provide you with information about what pharmaceutical or other business concerns are involved in this controversy. Pfizer is the named defendant but Monsanto and Pharmacia were involved with the development of Celebrex, the drug at the heart of this dispute. Both of these companies have merged into Pfizer, except that Monsanto still has a separate agriculture company. I hope that this material is helpful to you in considering my request. Please feel free, however, to contact me should you desire additional information.

Sincerely,
Drew S. Days, III
Of Counsel
Morrison & Foerster LLP

1:30

2:30

737-5932

FAX: 202-75[illegible]

8/23/2004

LEXSEE 2004 U.S. APP. LEXIS 13784

UNIVERSITY OF ROCHESTER, Plaintiff-Appellant, v. G.D. SEARLE & CO., INC., MONSANTO COMPANY, PHARMACIA CORPORATION, and PFIZER INC., Defendants-Appellees.

03-1304

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

375 F.3d 1303; 2004 U.S. App. LEXIS 13784; 71 U.S.P.Q.2D (BNA) 1545

July 2, 2004, Decided

PRIOR HISTORY: [**1] Appealed from: United States District Court for the Western District of New York. Judge David G. Larimer. *Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 2004 U.S. App. LEXIS 2458 (Fed. Cir., 2004)*

DISPOSITION: Petition for rehearing and rehearing, en banc, denied.

COUNSEL: Gerald P. Dodson, Morrison & Foerster, LLP, of Palo Alto, California, filed a petition for rehearing for plaintiff-appellant. With him on the petition were Emily A. Evans, Erica D. Wilson and Erik J. Olson.

Gerald Sobel, Kaye Scholer LLP, of New York, New York, filed an opposition to the petition for defendants-appellees. With him on the opposition were Richard G. Greco, Sylvia M. Becker and Daniel L. Reisner. Of counsel on the opposition was Robert L. Baechtold, Fitzpatrick, Cella, Harper & Scinto, of New York, New York.

Daniel J. Furniss, Townsend and Townsend and Crew LLP, of Palo Alto, California, filed an amici curiae brief for The Regents of the University of California, et al. With him on the brief were Susan M. Spaeth and Madison C. Jellins.

JUDGES: NEWMAN, Circuit Judge, dissents in a separate opinion. RADER, Circuit Judge, with whom GAJARSA and LINN, Circuit Judges, join, dissents in a separate opinion. LINN, Circuit Judge, with whom RADER and GAJARSA, Circuit Judges, join, dissents in a separate opinion. LOURIE, Circuit Judge, concurs in a separate opinion. [**2] DYK, Circuit Judge, concurs in a separate opinion.

OPINION:

[*1303] ON PETITION FOR REHEARING EN BANC

ORDER

A petition for rehearing en banc was filed by the Appellant, and a response thereto was invited by the court and filed by the Appellees n1 .

n1 The Regents of the University of California, et al. filed an amici curiae brief.

This matter was referred first as a petition for rehearing to the merits panel that heard this appeal. Thereafter, the petition for rehearing en banc, response, and the amici curiae brief were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

[*1304] (1) The petition for rehearing is denied.

(2) The petition for rehearing en banc is denied.

NEWMAN, Circuit Judge, dissents in a separate opinion.

LOURIE, Circuit Judge, concurs in a separate opinion.

RADER, Circuit Judge, with whom GAJARSA and LINN, Circuit Judges, join, dissents in **[**3]** a separate opinion.

LINN, Circuit Judge, with whom RADER and GAJARSA, Circuit Judges, join, dissents in a separate opinion.

DYK, Circuit Judge, concurs in a separate opinion.

The mandate of the court will issue on July 9, 2004.

July 2, 2004
Date

CONCURBY: LOURIE; DYK

CONCUR: LOURIE, Circuit Judge, concurring.

I concur in the decision of the court not to rehear this case en banc, just as previously the court also declined to hear a written description case en banc. See *Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 970-75 (Fed. Cir. 2002)*. That is because this case was properly decided based on one of the grounds relied on by the district court in invalidating the Rochester patent, see *Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004)*, the analysis of which will not be repeated here.

Contrary to the assertions of the appellant, certain amici, and some of the dissenters, there is and always has been a separate written description requirement in the patent law. The requirement to describe one's invention is basic to the patent law, and every patent draftsman knows that he or she must describe **[**4]** a client's invention independently of the need to enable one skilled in the relevant art to make and use the invention. The specification then must also describe how to make and use the invention (i.e., enable it), but that is a different task.

The requirements of the statute cannot be swept away by claiming that it relates only to priority issues or that the prohibition on introduction of new matter takes care of the need for a written description. The statute does not contain a limitation that it pertains only to priority issues. Moreover, the prohibition on introduction of new matter (*35 U.S.C. § 132*) is not a substitute for the written description requirement. *Section 282 of the Patent Act* lists as a defense to an infringement action invalidity arising from a failure to comply with a requirement of *section 112 of the Act*, which includes written description. In contrast, the new matter provision, *section 132*, appears in a provision entitled "Notice of rejection; reexamination." Failure to comply with that section is not expressly listed in the statute as an invalidity defense to infringement, although we have held that the unsupported claims are invalid. **[**5]** See, e.g., *Quantum Corp. v. Rodime, PLC, 65 F.3d 1577 (Fed. Cir. 1995)* (invalidating claims that were broadened in scope during reexamination in violation of **[*1306]** *35 U.S.C. § 305*, which is analogous to *section 132*).

The separate written description requirement poses no conflict with the role of the claims. It is well established that the specification teaches an invention, whereas the claims define the right to exclude. *SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985)*. While claims must be supported by the written description, the latter contains much material that is not in the claims. The written description contains an elucidation of various aspects of an invention as well as material that is necessary for enablement. Moreover, the written description often contains material that an applicant intended to claim that has been rejected in examination. Thus, the written description and the claims do not duplicate each other.

The fact, if it is a fact, that written description has only been relied upon in recent years as a ground of invalidity does not remove that requirement from the statute. **[**6]** Legal holdings arise when they do because litigants raise them and courts have to decide them. Contrary to what has been asserted, the interpretation of the statute as containing a separate written description requirement did not originate with Lilly. See *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991)*; *In re Ruschig, 54 C.C.P.A. 1551, 379 F.2d 990 (CCPA 1967)*. It has always been there. And if a particular scope of claim has not been sustained by the courts for failure to comply with the written description requirement, it is because the applicant did not describe, and presumably did not invent, the subject matter of the scope sought.

Moreover, it is not correct, as has been asserted, that our decisions, particularly *Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997)*, have created a "heightened" written description requirement for biotechnology inventions. We have applied the written description requirement to cases that are not in the fields of chemistry or biotechnology. See, e.g., *In re Curtis, 354 F.3d 1347 (Fed. Cir. 2004)* (dental floss); *Tronzo v. Biomet, Inc., 156 F.3d 1154 (Fed. Cir. 1998)* [**7] (artificial hip sockets); *Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998)* (sectional sofas); *Lockwood v. Am. Airlines, Inc., 107 F.3d 1565 (Fed. Cir. 1997)* (automated sales terminals); Vas-Cath (double lumen catheters). The statute is the same for all types of inventions, although it may be applied differently, based on the technology and what is known by one of ordinary skill in the art at the time an invention was made. Indeed, Rochester's claimed invention at issue in the present case is not biotechnological. Although the inventors apparently contemplated that the tools of biotechnology would be used to determine whether a given drug is a COX-2 inhibitor insofar as the specification of the '850 patent

describes how to make cell lines that express one or the other of COX-1 and COX-2, that method is claimed in another patent. The claims of this patent are all directed to pharmaceutical methods for selectively inhibiting a natural process in the human body. That is not what one commonly refers to as biotechnology.

It has been noted that genes can be described by their informational function, not just by structure or physical [**8] or chemical properties, and that a lesser written description may be adequate than is required for other types of inventions. Maybe so. Technology progresses, and what one skilled in the art would read from a particular disclosure may change. The PTO has now provided guidelines that help to guide applicants in preparing their patent applications.

It is obviously correct that genes convey information (e.g., to make other nucleic [*1307] acids or to encode particular proteins). That fact does not serve to deny the existence of a written description requirement in the law. It only goes to whether, under the facts of a particular case, the written description requirement has been met. A fact-finder may have to decide whether claiming a material solely by its information-conveying character results in a "single means claim" purporting to claim everything that works, a dubious fulfillment of the requirement to "distinctly claim the subject matter" of the invention. *35 U.S.C. § 112*. In any event, it is fact-intensive. But, once again, these matters go to whether the written description requirement has been met, not whether it exists.

As for the proposition that an original [**9] claim is part of the written description, that is clear. See *In re Gardner, 475 F.2d 1389, 1391 (CCPA 1973)*. However, the issue may still remain in a given case, especially with regard to generic claims, whether an original claim conveys that one has possession of and thus has invented species sufficient to constitute the genus. Thus, the fact that a statement of an invention is in an original claim does not necessarily end all inquiry as to the satisfaction of the written description requirement. See *Enzo, 323 F.3d at 968-69* ("Regardless whether the claim appears in the original specification and is thus supported by the specification as of the filing date, *§ 112*, P 1 is not necessarily met. . . . If a purported description of an invention does not meet the requirements of the statute, the fact that it appears as an original claim or in the specification does not save it. A claim does not become more descriptive by its repetition, or its longevity.").

In sum, I concur in the decision of the court not to rehear this case en banc. Our precedent is clear and consistent and necessitates no revision of written description law.

DYK, Circuit [**10] Judge, concurring in the court's decision not to hear the case en banc.

In my view the question of whether *35 U.S.C. § 112* contains a written description requirement (separate from the enablement requirement) does not merit en banc review. For the reasons set forth in the panel opinion and in Judge Lourie's opinion concurring in the denial of en banc review, I think it is clear that the statute contains such a requirement - applicable both in the context of priority and validity disputes. In this particular case the failure to satisfy that requirement was not even a close case. The appellant simply did not invent, much less describe, what was claimed.

My vote to deny en banc review, however, should not be taken as an endorsement of our existing written description jurisprudence. In my view we have yet to articulate satisfactory standards that can be applied to all technologies. Future panel opinions may provide the necessary clarity. If not, there may be a time when en banc consideration of the proper written description standards will be appropriate. But this is neither the right time, nor the right case, in which to consider those difficult [**11] questions.

DISSENTBY: NEWMAN Linn ; RADER

DISSENT: NEWMAN, Circuit Judge, dissenting from the denial of rehearing en banc.

I respectfully dissent from the court's decision not to resolve en banc the burgeoning conflict in pronouncements of this court concerning the written description and enablement requirements of the Patent Act. This question has been promoted from simple semantics into a fundamental conflict concerning patent scope and the support needed to claim biological products. The appropriate forum is now the en banc tribunal, not continuing debate in panel opinions applying divergent law.

I fully share Judge Lourie's understanding of the law. The continuing attack on well-established and heretofore unchallenged decisions such as *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991)* ("we hereby reaffirm, that *35 U.S.C. § 112*, first paragraph , requires a 'written description of the invention' which is separate and distinct from the enablement requirement") and earlier cases such as *In re Ruschig, 54 C.C.P.A. 1551, 379 F.2d 990 (CCPA 1967)* (written description is one of three distinct requirements under *35 U.S.C. § 112*) [**12] is not only unwarranted, but is disruptive of the stability with which this court is charged. If precedent has become obsolete or inapplicable, we should resolve the matter as a court and again speak with one voice.

> The new biology has indeed raised new and important questions, with implications for policy as well as law. However, the answer is not the simplistic one espoused by some commentators; it is simply incorrect to say that there is not now and never has been a "written description" requirement in the patent law. It has always been necessary to disclose and describe what is patented. It has never been the law that one can claim what is not made known and set forth in the patent.

Various past decisions have been offered to support the exotic proposition that it is not necessary for the inventor to describe the patented invention, but that enablement alone suffices under the statute. These cases concern traditional issues of generic disclosures and specific examples, and questions of support and predictability for scientific concepts and their embodiments. Such traditional law was applied in *Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997),* **[**13]** a case that is misdescribed in this debate, for Lilly does not depart from precedent in its holding that the written description requirement can be fulfilled by "a precise definition, such as by structure, formula, chemical name, or physical properties." *Id. at 1565*, quoting *Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993).*

If the nature of the subject matter is not amenable to precise description, some alternative mode of disclosure is required, such as deposit in a public depository. *Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956 (Fed. Cir. 2002).* However, the public purpose of patents is seriously disserved by eliminating the description requirement entirely. Federal Circuit law **[*1305]** of written description has become encumbered with inconsistent pronouncements, leading me to remark that "claims to an invention that is not described in the specification are an anachronism." *Housey Pharms., Inc. v. Astrazeneca UK Ltd., 366 F.3d 1348, 1357 (Fed. Cir. 2004)* (Newman, J., dissenting). If the majority of this court is nonetheless sympathetic to that position, there should be careful consideration of the implications [**14] of precedent, for the law is that "*Section 112* requires that the application describe, enable, and set forth the best mode of carrying out the invention." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 724, 152 L. Ed. 2d 944, 122 S. Ct. 1831 (2002).*

The issue of whether patent law contains a separate written description requirement has percolated through various panels of this court, on a variety of facts. The differences of opinion among the judges of the Federal Circuit, are, in microcosm, the "percolation" that scholars feared would be lost by a national court at the circuit level. Percolation is the great justifier of conflict among the regional circuits. In the words of the Supreme Court:

> We have in many instances recognized that when frontier legal problems are presented, periods of "percolation" in, and diverse opinions from, state and federal appellate courts may yield a better informed and more enduring final pronouncement by this Court.

Arizona v. Evans, 514 U.S. 1, 24 n.1, 131 L. Ed. 2d 34, 115 S. Ct. 1185 (1995). This question has percolated enough; it is ripe for en banc resolution.

LINN, Circuit Judge, with whom RADER and **[**15]** GAJARSA, Circuit Judges, join, dissenting from the court's decision not to hear the case en banc.

The panel opinion in this case perpetuates the confusion our precedent in Lilly and Enzo has engendered in establishing "written description" as a separate requirement of *35 U.S.C. § 112*, paragraph 1, on which a patent may be held invalid. That precedent should be overturned. Accordingly, I respectfully dissent from the court's decision not to hear this case en banc.

Section 112 of Title 35 of the United States Code requires a written description of the invention, but the measure of the sufficiency of that written description in meeting the conditions of patentability in *paragraph 1* of that statute depends solely on whether it enables any person skilled in the art to which the invention pertains to make and use the claimed invention and sets forth the best mode of carrying out the invention. The question presented by *35 U.S.C. § 112*, paragraph 1, is not, "Does the written description disclose what the invention is?" The question is, "Does the written description describe the invention recited in the claims--themselves part of **[**16]** the specification--in terms that are sufficient to enable one of skill in the art to make and use the claimed invention and practice the best mode contemplated by the inventor?" That is the mandate of the statute and is all our precedent demanded prior to *Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).*

Reading into paragraph 1 of *section 112* an independent written description requirement, divorced from enablement, sets up an inevitable clash between the claims and the written description as the focus of the scope of coverage. This is ill-advised. Surely there is no principle more firmly established in patent law than the primacy of the claims in establishing the bounds of the right to exclude. See, e.g., *Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 339, 5 L. Ed. 2d 592, 81 S. Ct. 599, 1961 Dec. Comm'r Pat. 635 (1961)* ("The claims made in the patent are the sole measure of the grant."); *McClain v. Ortmayer, 141 U.S. 419, 424, 35 L. Ed. 800, 12 S. Ct. 76, 1891 Dec. Comm'r Pat. 532 (1891)*

("'The rights of the plaintiff depend upon the claim in his patent, according to its proper construction.'" (quoting *Masury v. Anderson, 11 Blatchf. 162, 16 F. Cas. 1087, 1088, F. Cas. No. 9270 (C.C.S.D.N.Y. 1873)*)); **[**17]** *White v. Dunbar, 119 U.S. 47, 52, 30 L. Ed. 303, 7 S. Ct. 72, 1886 Dec. Comm'r Pat. 494 (1886)* ("The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms."); *Burns v. Meyer, 100 U.S. 671, 672, 25 L. Ed. 738 (1879)* ("The terms of the claim in letters-patent . . . define[] what the office, after a full examination of previous inventions and the state of the art, determines the applicant is entitled to."); *Merrill v. Yeomans, 94 U.S. 568, 570, 24 L. Ed. 235, 1877 Dec. Comm'r Pat. 279 (1876)* ("This distinct and formal claim is, therefore, of primary importance, in the effort to ascertain precisely what it is that is patented."); *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., 285 F.3d 1046, 1052 (Fed. Cir. 2002)* (en banc) ("Consistent with its scope definition and notice functions, the claim requirement presupposes that a patent applicant defines his invention in the claims, not in the specification. After all, the claims, not the specification, provide the measure of the **[**18]** patentee's right to exclude."); *SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985)* ("Specifications teach. Claims claim."). The statute itself makes clear that Congress intended the claims to define the scope of coverage. *35 U.S.C. § 112 P 2 (2000)*, ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.").

The primary role of the written description is to support the claims, assuring that persons skilled in the art can make and use the claimed invention. *Id. P 1* ("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."); see also *Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419, 1421 (Fed. Cir. 1987)* ("The purpose of the [written] description requirement . . . is to state what is needed to fulfil the enablement criteria. [**19] "); cf. *In re Barker, 559 F.2d 588, 594 (CCPA 1977)* (Markey, C.J., dissenting) ("The attempt to create historical and current statutory support for a 'separate description' requirement, which was solely a judicial (and unnecessary) response to chemical cases in which appellants were arguing that those skilled in the art 'might' make and use a claimed invention, is mistaken.").

Construing *section 112* to contain a separate written description requirement beyond enablement and best mode creates confusion as to where the public and the courts should look to determine the scope of the patentee's right to exclude. Under the panel's analysis, a court looks to the written description to determine the parameters of the patentee's invention--under guidelines yet to be articulated--and then determines if the claims, as properly construed, exceed those parameters. See *Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 922-23 (Fed. Cir. 2004)* ("While it is true that this court and its predecessor have repeatedly held that claimed subject matter 'need not be described in haec verba' in the specification to satisfy the written description requirement, it is also **[**20]** true that the requirement must still be met in some way so as to 'describe the claimed invention so that one skilled in the art can recognize what is claimed.'" (citations omitted)). There is simply no reason to interpret *section 112* to require applicants for patent to set forth the metes and bounds of the claimed invention in two separate places in the application. That is the exclusive function of the claims.

The burden of Lilly and Enzo has fallen on the biotech industry disproportionately, but, as this decision makes clear, the new-found written description requirement will affect all fields of emerging technology. *Univ. of Rochester, 358 F.3d at 925* (rejecting a limitation of the Lilly written description doctrine to genetic inventions on the ground that "the statute applies to all types of inventions"). When patent attorneys set out to write patent applications, they do so for an educated audience--those skilled in the art--and attempt to describe the invention in a way that enables those of ordinary skill to make and use the invention as claimed. Before the decision in Lilly, the practicing bar had accepted and found workable the notion elucidated **[**21]** in our precedent that *§ 112* requires a written description sufficient to enable one of ordinary skill in the art to make and use the claimed invention--i.e., enablement. Lilly changed the landscape and set in motion the debate the panel opinion in this case perpetuates.

As I commented in my dissent from the court's decision not to hear the Enzo case en banc, "Some have praised Lilly for maintaining the integrity of patent disclosures and for curbing patent filings for inventions that have not yet been made but are just nascent ideas. Others have been sharply critical of Lilly." *Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 989 (Fed. Cir. 2002)* (Linn, J., dissenting). That debate continues to leave uncertain how inventions are protected, how the United States Patent and Trademark Office discharges its responsibilities, and how business is conducted in emerging fields of law. These uncertainties will remain unless resolved by this court en banc or by the Supreme

Court. The issue is important, is ripe for consideration, and deserves to be clarified, one way or the other. For these reasons, I respectfully dissent from the court's refusal to consider [**22] this case en banc.

RADER, Circuit Judge, dissenting from the court's decision not to hear the case en banc, with whom Circuit Judges GAJARSA and LINN, join.

By a narrow margin, n1 this court has declined to take this case en banc. Thus, this court avoids the opportunity to clarify and correct its confusing jurisprudence on the new written description invalidity doctrine.

n1 Circuit Judges Newman, Rader, Bryson, Gajarsa, and Linn voted in favor of en banc reconsideration. Chief Judge Mayer and Circuit Judges Michel, Lourie, Clevenger, Schall, Dyk, and Prost voted against en banc reconsideration.

In 1997, this court for the first time applied the written description language of *35 U.S.C. § 112, P 1* as a general disclosure requirement in place of enablement, rather than in its traditional role as a doctrine to prevent applicants from adding new inventions to an older disclosure. *Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).* [**23] In simple terms, contrary to logic and the statute itself, Eli Lilly requires one part of the specification (the written description) to provide "adequate support" for another part of the specification (the claims). n2 [*1308] Neither Eli Lilly nor this case has explained either the legal basis for this new validity requirement or the standard for "adequate support." Because this new judge-made doctrine has created enormous confusion which this court declines to resolve, I respectfully dissent.

n2 This new validity requirement conflicts with binding precedent because the CCPA made clear that original claims are part of the original disclosure of an invention and thus have no "description" problems. *In re Koller, 613 F.2d 819, 823 (CCPA 1980)* ("Original claims constitute their own description."); *In re Smith, 481 F.2d 910, 914 (CCPA 1973)* ("Where the claim is an original claim, the underlying concept of insuring disclosure as of the filing date is satisfied, and the description requirement has likewise been held to be satisfied."); *In re Gardner, 475 F.2d 1389, 1391 (CCPA 1973)* ("Claim 2, which apparently was an original claim, in itself constituted a description in the original disclosure . . . . Nothing more is necessary for compliance with the description requirement.")

[**24]

Confusion in This New Validity Doctrine

A recent case illustrates well the confusion engendered by this new doctrine. In *Enzo Biochem, Inc. v. Gen Probe, Inc., 323 F.3d 956 (Fed. Cir. 2002)*, this court struggled over the scope of the written description invalidity doctrine first created in 1997. *Eli Lilly, 119 F.3d at 1559.* In its original Enzo opinion, *285 F.3d 1013 (Fed. Cir. 2002)*, this court invalidated claims to polypeptides that detect the gonorrhea bacteria. The inventor of these DNA probes specifically disclosed them and deposited three polypeptides at the American Type Culture Collection. Even for claims limited in scope to the deposited material, this court invalidated the patent for insufficient disclosure of the invention. *Id. at 1022* (concluding that "a deposit is not a substitute for a written description of the claimed invention" (quotation omitted)). This decision correctly applied the 1997 Eli Lilly doctrine which requires a nucleotide-by-nucleotide recitation of the structure of a biotechnological invention. *Eli Lilly, 119 F.3d at 1567.* Accordingly, the mere deposit of material [**25] did not satisfy that reading of *35 U.S.C. § 112, P 1. Enzo, 285 F.3d at 1022.*

That Enzo opinion caused an immediate firestorm. See, e.g., Brief of Amicus Curiae United States at 1, *Enzo Biochem, Inc. v. Gen Probe, Inc., 323 F.3d 956 (Fed. Cir. 2002).* Within a few months, this court vacated its original opinion and reversed the result. See *Enzo Biochem, Inc. v. Gen Probe, Inc., 323 F.3d 956 (Fed. Cir. 2002).* This flip-flop shows the problem. The Director of the Intellectual Property program at the George Washington University Law School stated it concisely: "Since the first panel opinion faithfully followed Eli Lilly, and the result is obviously wrong, the Eli Lilly description doctrine is itself misguided." Martin J. Adelman, If Eli Lilly Is Good Law, Didn't the Withdrawn Panel Opinion in Enzo Biochem Have It Right?, at 2 (2003) (unpublished paper prepared for the 11th Annual Conference on International Intellectual Property Law and Policy at Fordham University, April 24-25, 2003).

Following issuance, withdrawal, and reissuance of Enzo, this court engaged in lengthy debate over the [**26] new disclosure validity doctrine. *Enzo Biochem, 323 F.3d at 971-75* (Lourie, J., concurring in decision to not hear the case en banc); *id. at 975* (Newman, J., concurring); *id. at 975-76* (Dyk, J., concurring); *id. at 976-87* (Rader, J., dissenting) n3; *id. at 987-89* (Linn, J., dissenting). That debate continued in this court's subsequent cases. See, e.g., *Moba B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1323 (Fed. Cir. 2003)* [*1309] (Rader, J., concurring)

(explaining that juries face the "cumbersome task" of deciding that "the patent's disclosure can enable a skilled artisan to make and practice the entire invention, but still not inform that same artisan that the inventor was in possession of the invention").

n3 This opinion will not repeat the points made earlier about the legal sufficiency of the Eli Lilly doctrine. Some of those points include: First, the statutory language and legal precedents make enablement the only substantive test (other than best mode) in the first paragraph of *§ 112. Enzo Biochem, 323 F.3d at 977.* Second, this court's predecessor first separated written description from enablement in 1967, but only to police priority. Id. Third, this court and its predecessor consistently limited the written description requirement to priority cases, expressly equating the proscription on new matter with written description. *Id. at 977-79.* Lastly, the vague and ill-defined written description requirement threatens to supplant the well-established enablement requirement, which disproportionately affects biotech inventions. *Id. at 981- 83.*

[27]**

Indeed a brief survey of the literature on this topic, an astounding amount in a few short years, shows 31 articles criticizing the Eli Lilly doctrine, 7 articles defending the doctrine, and 16 neutrally commenting on the state of this evolving case law. n4 In its brief requesting en banc reconsideration in Enzo Biochem, the United States issued a call for clarity, which this court has yet to address:

> Although this Court has addressed the "written description" requirement of *section 112* on a number of occasions, its decisions have not taken a clear and uniform position regarding the purpose and meaning of the requirement. . . . A review of the plain text of *section 112*, and the case law of this Court, reveals at least three different possible tests for an adequate "written description." . . . En banc consideration of the written description provision is appropriate so that the court can provide inventors, the public, and the USPTO with an authoritative interpretation of the provision.

Brief of Amicus Curiae United States at 4-5, 9.

N4 An appendix to this opinion summarizes this academic commentary.

[28]**

In sum, by any measure, the Eli Lilly doctrine has engendered confusion. After all, Eli Lilly created a new validity doctrine under *35 U.S.C. § 112, P 1* separate from enablement and yet described it as "analogous to enablement." *119 F.3d at 1569.* Unfortunately, this court has passed up another opportunity to resolve the confusion.

Supreme Court's Role in the Eli Lilly Doctrine

In an effort to supply some coherent basis for its new validity doctrine, this court in Rochester refers to an 1822 Supreme Court case that discusses the written description language of the Patent Act. *Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 924 (Fed. Cir. 2004).* An examination of Rochester's references to the Supreme Court in their proper historical context impeaches, rather than supports, the modern written description validity doctrine.

In 1793, the Patent Act, 1 Stat. 318, required an inventor to describe the scope of the invention in the body of the specification; the Act did not require any claims. Instead the Act required the inventor to provide "a written description of his invention, and of the manner of **[**29]** using, or process of compounding the same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science . . . to make, compound, and use the same. . . ." *In re Barker, 559 F.2d 588, 592 (CCPA 1977)* (ellipses in original). Without citing this statutory language, Rochester recounts the Supreme Court's explanation that this provision contained two requirements:

> The specification, then, has two objects: one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent. . . . The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an [*1310] invention which the party may otherwise innocently suppose not to be patented.

Evans v. Eaton, 20 U.S. 356, 433-34, 5 L. Ed. 472 (1822). For obvious **[**30]** reasons, Rochester undertakes no further explanation of the Supreme Court's language. In simple terms, the Supreme Court could not have meant that the written description portion of the specification must provide adequate support for the claims as this court's law presently requires. Patents did not even contain claims in 1822.

In fact, even the Supreme Court's allusion to "two objects," the reason for the Rochester cite, takes on a different meaning under careful legal analysis. The Supreme Court clearly linked its "other object" of the specification disclosure to the portion of the statute requiring the inventor "to distinguish the same from all things before known." *Evans, 20 U.S. at 430.* Significantly, that language no longer appears in *35 U.S.C. § 112.* Later in 1870, the Patent Act first articulated the requirement that applicants define their exclusive right in a distinctly drafted claim. Act of July 8, 1870, Ch. 230, 16 Stat. 198. Only one logical conclusion flows from this history. When the Patent Act assigned the notice function to claims rather than the written description, enablement became the sole *35 U.S.C. § 112 P 1,* **[**31]** standard for adequate disclosure of an invention. n5 See *Enzo Biochem, 323 F.3d at 977.* This observation about the meaning of *35 U.S.C. § 112, P 1* has been axiomatic patent law for decades. In a decision of the Court of Customs and Patent Appeals that is binding on this court, Judge Rich interpreted *35 U.S.C. § 112, P 1* to have only two requirements - not enablement and the Eli Lilly written description doctrine, but enablement and best mode! *In re Gay, 50 C.C.P.A. 725, 309 F.2d 769, 772, 1962 Dec. Comm'r Pat. 737 (CCPA 1962).* In sum, the Eli Lilly written description doctrine has no basis in this court's legal precedent. Thus, Rochester cannot explain the missing 1793 statutory language, the advent of the claim requirement that replaced the 1822 description doctrine, the inapplicability of the Evans quote to a new 1997 invalidity doctrine, or the apparent conflict with binding CCPA interpretations of *35 U.S.C. § 112, P 1.*

n5 Indeed the United States notes that the current statute requires "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 [the invention]." *35 U.S.C. § 112, P 1* (emphasis added). As the United States noted, "A straightforward reading of the text of *section 112* suggests that the test for an adequate written description is whether it provides enough written information for others to make and use the invention." Brief of Amicus Curiae United States at 5, *Enzo Biochem, Inc. v. Gen Probe, Inc., 323 F.3d 956 (Fed. Cir. 2002).*

[32]**

The Rochester reference to the 1822 Supreme Court language does, however, reveal some insights into the reasons that the Eli Lilly doctrine engenders confusion. As the 1822 Supreme Court reference explains, the original statute required a written description to warn "an innocent purchaser or other person using a machine, of his infringement." *Evans, 20 U.S. at 434.* In other words, the statute incorporated a written description requirement to define the scope of the invention for infringement and for distinguishing the invention from prior art. Eli Lilly and its progeny convert that original infringement doctrine into a new challenge to validity. Suddenly, all the difficulty and imprecision of defining an invention in legal language, see *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731, 152 L. Ed. 2d 944, 122 S. Ct. 1831 (2002),* becomes a validity doctrine.

In sum, a careful legal analysis of the language and history of *35 U.S.C. § 112, P 1* **[*1311]** shows that the Eli Lilly doctrine has no basis in the written description language of the original Patent Act. Moreover, as this court's binding CCPA precedent shows, **[**33]** the statutory language of *35 U.S.C. § 112, P 1* has not changed in any way that justifies "discovery" of a vast new validity doctrine over two hundred years after the 1793 Act. To the contrary, the changes in the statutory language of *§ 112, P 1* since 1793 impeach the reasoning of Rochester and Eli Lilly.

Rochester also refers to the Supreme Court's listing of patent requirements in *Festo. Rochester, 358 F.3d at 921* (quoting *Festo, 535 U.S. at 736*). In the first place, the Festo listing is just that, a passing reference to some of the requirements of the Patent Act. The passing reference, for instance, does not even mention some binding requirements, e.g., subject matter eligibility and claim definiteness. In fact, in another post-Eli Lilly listing of Patent Act requirements, the Supreme Court acknowledged only enablement as the disclosure quid pro quo of the statute: "In addition [to novelty, utility, and nonobviousness], to obtain a utility patent, a breeder must describe the plant with sufficient specificity to enable others to 'make and use' the invention after the patent term expires." *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142, 151 L. Ed. 2d 508, 122 S. Ct. 593 (2001).* [**34] A careful analysis of the Supreme Court's passing recitations of patent requirements does not support the Eli Lilly doctrine.

Rochester's invocation of the Festo listing of a "disclosure" requirement, however, betrays a telling incompleteness in its reasoning. The Supreme Court is entirely correct to acknowledge the requirement of full "disclosure" at the time of invention that prevents

updating the patent document with later inventions. Beginning in 1967, this court and its predecessor applied the written description language to achieve this vital purpose of the Patent Act - tying disclosure to the time of invention. *In re Ruschig, 54 C.C.P.A. 1551, 379 F.2d 990 (CCPA 1967)*; *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991)*. In the words of Judge Rich, the first judge to use the description requirement to police priority, "The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him." *In re Wertheim, 541 F.2d 257, 262 (CCPA 1976)* (emphasis added). In fact, every application [**35] of the written description doctrine before Eli Lilly in 1997 applied the written description doctrine for this important purpose and only for this important purpose. *Enzo, 323 F.3d at 984-87* (listing every written description case in the CCPA and Federal Circuit). Thus, the Festo listing does not endorse the Eli Lilly innovation, but properly invokes the necessity of tying disclosure to the time of invention. In its attempt to support the 1997 doctrine, however, Rochester invokes Vas-Cath and other Federal Circuit decisions without noting the proper context of those decisions.

In sum, the Supreme Court offers no comfort to the Eli Lilly doctrine. Rather, in proper historical and legal context, the Supreme Court's allusions to the description requirement impeach both Rochester and Eli Lilly. n6

n6 Moreover, the pre-1967 CCPA cases mentioned in Rochester also shed little light on the modern written description requirement. For instance, Jepson does not evince support for Eli Lilly. Rather, Jepson, which does not expressly mention written description at all, decided an interference - a priority dispute - between an application with an earlier filing date and an issued patent with a later filing date. The CCPA held that because the earlier application did not support the claims that were copied from the later patent, the patent was entitled to priority. *Jepson v. Coleman, 50 C.C.P.A. 1051, 314 F.2d 533, 1963 Dec. Comm'r Pat. 304 (CCPA 1963)*. Thus, Jepson, if at all relevant to written description, was a priority case in the traditional mode of written description jurisprudence. The CCPA decided the Moore case on obviousness grounds; the description commentary in that case is dicta. *In re Moore, 33 C.C.P.A. 1083, 155 F.2d 379, 381, 1946 Dec. Comm'r Pat. 421 (CCPA 1946)* (noting that the claims were "properly rejected on the prior art"). The CCPA decided the Sus case under paragraph 2 of *§ 112*, not *paragraph 1. In re Sus, 49 C.C.P.A. 1301, 306 F.2d 494, 496, 1962 Dec. Comm'r Pat. 486 (CCPA 1962)*. The reason Sus and Moore do not appear on the "written description" landscape is because subsequent case law made it clear that, outside the priority context, the substantive test for compliance with the first paragraph of *§ 112* is enablement. *In re Borkowski, 57 C.C.P.A. 946, 422 F.2d 904, 909 (CCPA 1970)*. Indeed, Rochester seems to do a disservice to the CCPA's own acknowledgement that Judge Rich inaugurated the written description requirement to police priority in 1967. *In re Rasmussen, 650 F.2d 1212, 1214 (CCPA 1981)*.

[**36]

[*1312] The Hypothetical Policy Analysis

Rochester refers to a situation where a patent can enable an invention that is not described by the specification. In the words of the opinion, "such can occur when enablement of a closely related invention A that is both described and enabled would similarly enable an invention B if B were described." *Rochester, 358 F.3d at 921* (emphasis original). This hypothetical seems to suggest that the 1997 doctrinal creation closes a major gap in patent law. To the contrary, this court only created the Eli Lilly requirement in 1997; the patent system had succeeded quite well for over two hundred years without it. Moreover no other patent system in the world has the Eli Lilly requirement to this day. The world's patent systems work quite well without it.

The hypothetical actually facilitates a policy analysis that explains the reasons that the new 1997 requirement is both superfluous and dangerous. In the first place, the hypothetical rarely, if ever, happens. No actual case presents the hypothetical. In both Eli Lilly and Rochester, for instance, the invention A (rat insulin in Eli Lilly; an assay for Cox 1 [**37] and 2 in Rochester) was enabled and described, but the invention B (human insulin in Eli Lilly; a Cox 2 inhibitor in Rochester) was not enabled.

In understandable terms, the hypothetical says that an inventor invents the radio, but his invention solves a problem that enables those of ordinary skill in the art to know how to make and use both a radio and a TV. His patent disclosure only describes a radio but he claims broadly an "electrical receiver." Thus, his claims seem to encompass the TV which his specification does not describe but would enable if it were described. In that context, the reason the hypothetical does not occur becomes obvious. If everyone of ordinary skill in the art knows from the disclosure how to make and use the TV, the exceptionally talented inventor will also. To avoid any risk of losing the TV invention, the inventor will fully

disclose it and claim it, probably in a separate application. For this very practical reason, no case has ever presented the hypothetical. Inventors know when they have made an invention and realize that they must properly disclose it or risk losing it entirely.

Carrying the genuinely "hypothetical" hypothetical [**38] forward, however, what happens if the radio inventor for some unfathomable reason does not grasp that he has enabled a TV and later asserts the radio patent against a TV maker? In simple terms, a court would properly interpret the claim as limited to the radio. The TV maker would not infringe a claim that covers only the radio. On the other hand, the Eli Lilly doctrine would instead invalidate the radio patent. Is that the best result? After all, the inventor did invent the radio. [*1313] Should he lose everything because he did not disclose the TV?

The facts of Eli Lilly itself illustrate the real problems in this area of patent interpretation and enforcement. In simple terms, the inventor in that case invented and disclosed rat insulin but not human insulin. In fact, at the dawn of the biotechnological age in 1977, the inventor could not make human insulin. Biotechnology was in its infancy; it would have taken months, if not years, of experimentation to make human insulin. Nonetheless the inventor claimed the rat insulin invention broadly and later asserted it against human insulin. In this setting, U.S. patent law (and world patent law in general) has two complementary ways to [**39] prevent any injustice - enablement and traditional (not Eli Lilly) written description (enforcing the actual time of invention). If the inventor has not enabled human insulin in the specification, the inventor has not enabled the full scope of the claim. By the way, as noted earlier, if the rat insulin inventor had invented human insulin as well, he surely would have disclosed it. In other words, a lack of disclosure is a dead give-away for enablement problems. Alternatively, or likely in conjunction, the traditional written description requirement as applied by this court and its predecessor beginning in 1967 will prohibit any addition of new matter to the patent document to "update" the claims to cover human insulin. See, e.g., *Chiron Corp. v. Genentech, Inc., 363 F.3d 1247 (Fed. Cir. 2004)*.

In sum, our patent law (and the world's patent law) has worked well for 200 years because the law already possesses ample remedies for the Rochester hypothetical, which, as a practical matter, never occurs. Neither Eli Lilly nor Rochester explains the legal policy that supports the new doctrine.

The Practical Problems

By its terms, the Eli Lilly doctrine [**40] stated: "An adequate written description of a DNA . . . 'requires a precise definition, such as by structure, formula, chemical name, or physical properties.'" *119 F.3d at 1566* (quoting *Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993)*). In sum, Eli Lilly asserts a new free-standing validity requirement. Based on the absence of a nucleotide-by-nucleotide recitation in the specification of the human insulin cDNA, the court determined that the applicant had not adequately described the invention. Thus, the failure to actually sequence the nucleotides prevents an applicant from claiming a new and useful polypeptide.

This new 1997 rule changes the established rules of claiming and disclosing inventions. Many biotechnological inventions predate Eli Lilly. Before the 1997 change, no inventor could have foreseen that the Federal Circuit would make a new disclosure rule. Without any way to redraft issued patents to accommodate the new rule, many patents in the field of biotechnology face serious and unavoidable validity challenges simply because the patent drafter may not have included the lengthy nucleotide sequences. After all, the sequences are [**41] often routinely available (albeit at some cost) to those of ordinary skill in this art.

The Eli Lilly doctrine also seems to impose some illogical requirements on patent drafters today. Must a software patent disclose every potential coding variation that performs a claimed [*1314] function? Must a biotechnological invention list every amino acid variation for a particular protein or protein function - a task conceivably as impractical as the software disclosure requirement? Must a university or small biotech company expend scarce resources to produce every potential nucleotide sequence that exhibits their inventive functions? Perhaps more important for overall patent policy, must inventors spend their valuable time and resources fleshing out all the obvious variants of their last invention instead of pursuing their next significant advance in the useful arts? Again Eli Lilly and Rochester appear to have given little thought to these unintended consequences.

This court, however, is not even the only judicial institution that must deal with the unintended consequences of the 1997 doctrine. Under this new disclosure test, every case where the written description does not specifically [**42] disclose some feature of the claimed invention will give rise to a validity challenge. Thus, trial courts will have to empanel juries to inquire whether one of skill in the art would have known that the inventor "possessed" the full invention. In a sense, the Eli Lilly doctrine converts this court's confusing case law about the role of the specification in defining the invention into a validity question. Thus, trial courts as well must struggle to discern the standard for sufficient disclosure of an invention.

Rochester emphasizes that this new disclosure doctrine is different from enablement. *Rochester, 358 F.3d at 921*. Thus, a trial court, as in this case, must first ask its jury whether the specification provides sufficient information to enable one of ordinary skill in the art to make and use the invention. Then the trial court must ask the jury again to look at the same specification for information that an inventor of extraordinary skill "possessed" the invention. Under this court's law, a patent disclosure could apparently enable one of ordinary skill to make and practice the entire invention, but still not inform that same artisan that the inventor [**43] was in possession of the invention. Moreover, the trial court must give separate instructions and entertain separate witnesses on these inseparable patent rules to ensure adequate disclosure. Viewed in the practical terms of trial procedure and jury understanding, this 1997 doctrine unnecessarily complicates and prolongs patent enforcement. In sum, Rochester does not resolve any of the confusion or provide a sound legal basis for the Eli Lilly doctrine. For these reasons, this court should have reviewed this case en banc.

APPENDIX

Defending Eli Lilly Written Description

Citation	Quotation
Paula K. Davis, Questioning the Requirement for Written Description: Enzo Biochem v. Gen-Probe and Overly Broad Patent Cases, *37 Ind. L. Rev. 467*, 500 (2004)	By strictly requiring written description of the invention, the public is guaranteed that the inventor was in possession of the invention when the patent application was filed. In effect, the written description defines the scope of the invention- the metes and bounds that will be given exclusivity.
F. Scott Kieff, The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules, *45 B.C. L. Rev. 55, 99 (2003)*	The U.S. Court of Appeals for the Federal Circuit's strong reading of the written description requirement to put the public on clear notice of what will infringe and what will not makes sense because the patentee, as the drafter, is the least-cost avoider of such ambiguities. This legal development was controversial to be sure; yet it marks an important weapon in the system's arsenal for fighting social cost.

Cynthia M. Lambert, Note: Gentry Gallery and the Written Description Requirement, *7 B.U. J. Sci. & Tech. L. 109, 139 (2001)*	Although there may be negative effects resulting from a stricter written description standard, including narrowed patent scope and a potential tragedy of the anticommons, the stricter standard is the better choice in terms of fairness to the public because it prevents inventors from overreaching.
Daniel P. Chisholm, Note: The Effect of the USPTO's Written Description Guidelines on Gene Patent Applications, *35 Suffolk U. L. Rev. 543, 570 (2001)*	Absent this heightened interpretation, broadly construed claims would allow applicants to obtain exclusive rights to products in which they do not actually possess. Granting such broad claims would stifle the very purpose of the United States patent system: preserving incentives for continued innovations.
Margaret Sampson, Comment: The Evolution	The use of a heightened written

of the Enablement and Written Description Requirements Under *35 U.S.C. 112* in the Area of Biotechnology, *15 Berkeley Tech. L.J. 1233, 1273 (2000)*	description requirement by the Federal Circuit to define and limit the scope of claimed inventions preserves incentives for continued innovation.
Mark J. Stewart, Note: The Written Description Requirement of *35 U.S.C. 112*(1): The Standard After Regents of the University of California v. Eli Lilly & Co., *32 Ind. L. Rev. 537, 563 (1999)*	Through application of the written description requirement, courts can distinguish between claims to technologies that are too broad or basic to justify patent protection, and those dealing with other types of technologies that are more predictable and may justify broader protection.
Emanuel Vacchiano, Comment: It's a Wonderful Genome: The Written-Description Requirement Protects the Human Genome from Overly-Broad Patents, *32 J.Marshall L. Rev. 805, 832 (1999)*	Fortunately, the CAFC narrowly construes patent rights based on disclosures of DNA sequences, and as a result, will likely invalidate patent claims based on EST disclosures that contain a broad scope of protection encompassing a gene or even an entire protein-coding segment of a cDNA.

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Criticizing Eli Lilly Written Description

Citation	Quotation
Stephen J. Burdick, Note: Moba v. Diamond Automation, Inc.: Questioning the Separate Written Description Requirement, *19 Berkeley Tech. L.J. 133, 151 (2004)*	Moba illustrates the problems associated with the separate written description requirement. The judge-made doctrine does not contribute any additional value to the other patentability requirements. Its effects are redundant with the enablement and new matter requirements of patent law. Additionally, the written description requirement creates confusion and discourages patenting and innovation. The Federal Circuit should dispose of the separate written description requirement entirely.
Martin J. Adelman, 3-2 Patent Law Perspectives § 2.9 (2004)	[T]he original panel opinion in , Enzo Biochem is correct if we assume that Eli Lilly is sound law since Eli Lilly holds that the failure to actually detail the sequence of nucleotides of a polypeptide prevents an applicant from claiming it. Obviously merely depositing a polypeptide does not disclose its sequence without a sequencing operation. Thus a disclosure that effectively puts the polypeptide in possession of the public by virtue of providing a set of directions for obtaining it should not be treated differently than an inventor who puts the polypeptide in a depository without sequencing it. Since this is a it result that is difficult do defend, proves that the Eli Lilly doctrine is itself misguided. It is thus time to formally overrule it along with In re Deuel another case that holds

	that the act of sequencing is the key to patentability.
Harold C. Wegner, The Disclosure Requirements of the 1952 Patent Act: Looking Back and a New Statute for the Next Fifty Years, *37 Akron L. Rev. 243, 244 (2004)*	The first problem here is the judicial activism from several panel opinions that created a "written description" requirement apart from the original "new matter" proscription.
Jennifer L. Davis, Comment: The Test of Primary Cloning: A New Approach to the Written Description Requirement in Biotechnological Patents, 20 Santa Clara Computer & High Tech. L.J. 469, 487-88 (2004)	The court has not issued clear and consistent standards. In fact, the court itself appears confused over the proper standards by which to judge the adequacy of a written description as reflected by the recent decision in Enzo I followed by a reversal upon rehearing in Enzo II. . . .
Martin J. Adelman, If Eli Lilly Is Good Law, Didn't the Withdrawn Panel Opinion in Enzo Biochem Have It Right?, at 2 (2003) (unpublished	[S]ince the first panel opinion [in Enzo] faithfully followed Eli Lilly, and the result reached is obviously wrong, the Eli Lilly description doctrine is itself

paper prepared for the 11th Annual Conference on International Intellectual Property Law and Policy at Fordham University, April 24-25, 2003).	misguided.
Duane M. Linstrom, Spontaneous Mutation: A Sudden Change in the Evolution of the Written Description Requirement as It Applies to Genetic Patents, *40 San Diego L. Rev. 947, 970 (2003)*	In sum, the latest Enzo decision has shifted the direction of the development of the written description requirement for DNA patents, but it has also left us with even more uncertainty in the law than before the ruling.
Jennifer Gordon, Ph.D., Preparing and Prosecuting a Patent That Holds Up in Litigation, 766 PLI/Pat 873, 907-08 (2003)	Until the dissenters can persuade the Court to review the Lilly written description rule en banc, the Federal Circuit can continue to apply the Lilly standard to invalidate any patent, regardless of whether priority is an issue, where the written description does not show possession of the invention at the time of filing.

Rachel Krevans and Cathleen Ellis, Preparing for Biotech Patent Litigation, 760 PLI/Pat 529, 555-56 (2003)	The Federal Circuit doctrine that makes enablement a separate requirement from the written description requirement contradicts the plain language of the statute.
John C. Stolpa, Case Comment: Toward Aligning the Law with Biology? The Federal Circuit's About Face in Enzo Biochem, Inc. v. Gen-Probe, Inc., *4 Minn. Intell. Prop. Rev. 339, 366 (2003)*	The Federal Circuit should take the next available opportunity to overrule the Eli Lilly decision through an en banc hearing and return enablement as the sole substantive disclosure requirement of *35 U.S.C. 112*, paragraph 1. The heightened written description standard applied to biotechnology inventions after Eli Lilly ignores fundamental biological principles and focuses too much attention on the structure of a DNA or protein. In addition, the standard is inflexible to technological changes and requires constant updating that leads to uncertainty over patent validity. Finally, the heightened requirement fails to meet the constitutional purpose behind the patent laws by discouraging full disclosure of biological inventions. Simply returning to the enablement disclosure standard that was in effect prior to Eli Lilly would solve the bulk of these problems.

Laurence H. Pretty, Patent Patent Litigation § 1:3.3, Defenses Against Validity, 1-44 (2003)	The term "written description" the appears grammatically as the subject for the verb "enable" in enablement section of *35 U.S.C. § 112*. However, the written-description requirement has been judicially construed to have a separate and additional purpose.
Stephen R. Albainy-Jenei and Karlyn A. Schnapp, Early-Stage Companies Face New Challenges Rochester Case Limited the Patentability Of Reach-Through Claims, 12/8/03 Nat'l L.J. S3, col. 1, S3, col. 1+ (2003)	While Rochester is on appeal to the U.S. Court of Appeals for the Federal Circuit, it is likely that such reach-through claims will remain severely restricted, possibly hurting the value of intellectual property for many early-stage biotechnology companies.* * * In addition, the overall cost in legal fees for drafting and prosecuting more carefully crafted, fully detailed biotechnology applications will only increase for complex inventions. While big pharmaceutical companies will have the money to spend in such endeavors, it will be the universities and the small biotech start-ups that will most certainly be affected since these have the of institutions historically do not resources, both financial and in personnel, to overcome this new set obstacles in trying to obtain patent protection for their scientific contributions in an ever-changing landscape.

Dan L. Burk and Mark A. Lemley, Policy Levers in Patent Law, *89 Va. L. Rev. 1575, 1652-54 (2003)*	In biotechnology, however, the of doctrine has been applied as a sort "super-enablement" requirement, forcing biotech patentees to list particular gene sequences in order to obtain a patent covering those sequences. The written description doctrine as currently applied is a macro policy lever. The Federal Circuit has applied the doctrine to biotechnology cases in a way that would be inconceivable in other industries, such as software. The effect is to narrow the scope of biotechnology patents--or at least DNA patents --rather dramatically.
Warren D. Woessner, "Do-Over!" - The Federal Circuit Takes a Second Look at Enzo v. Gen-Probe, *85 J. Pat. & Trademark Off. Soc'y 275, 285 (2003)*	It is time for the court to deliver Lilly and Enzo (I) to the doctrinal scrap heap where holdings like Durden and Druey ended up, and let the evolution of biotechnology patent law continue in a productive direction.
Robert L. Harmon, Must a Patent Describe an Accused Infringement?, *85 J. Pat. & Trademark Off. Soc'y 153, 154* (2003)	In the meantime, however, we are is confronted with a welter of confused and confusing precedent that not only defies restatement, but renders analysis and synthesis distinctly unmanageable. The only approach the author has found to making some sense of the situation to ask what the motivation of the Federal Circuit is in its efforts to restrict this once well-recognized tenet of patent law.

Sven J.R. Bostyn, Written the Real Description After Enzo Biochem: Can Requirement Step Forward Please?, *85 J. Pat. & Trademark Off. Soc'y 131,* 151 (2003)	The third way is to limit the where application of the written description requirement to cases priority issues are involved, and limiting it to these issues, leaving the bulk of the disclosure evaluation to the enablement requirement, the key feature of the quid pro quo of the patent system. In the author's view, that ought to be the optimal solution, leading to a coherent and stable patent system, both for patent applicants and for patent offices and courts. In this light, it would have been a good opportunity to hear the Enzo case en banc.

David Kelly, Comment: The Federal Circuit Transforms the Written Description Requirement into a Biotech-Specific Hurdle to Obtaining Patent Protection for Biotechnology Patents, *13 Alb. L.J. Sci. & Tech. 249,* 270 (2002)	The Federal Circuit's decision in Lilly, however, has fashioned the description requirement into a barrier to scientific progress in the field of biotechnology. This heightened standard, applied exclusively to biotechnology patents, patents, will likely have an adverse effect on the progress of biotechnological innovations. Rather than awarding patent protection to the discoverers of new and useful genes, Lilly rewards those who first sequence the gene accurately. The result will be patent protection to those who can

	sequence DNA the fastest, not to those who invested their life's work locating the gene.
Eli A. Loots, The 2001 USPTO Written Guidelines and Gene Claims, *17 Berkeley Tech. L.J. 117, 134 (2002)*	Some conflict between patent is the prosecution and patent litigation inevitable. However, the current conflict has been recognized as a widening gulf between the norms of scientific community and those of the legal system.
Limin Zheng, Purdue Pharma L.P. v. Faulding Inc., *17 Berkeley Tech. L.J. 95,* 103 (2002)	The court's continuing use of an is inconsistent and often overly- stringent written description requirement leaves inventors, especially those in the pharmaceutical industry, with little incentive to disclose, and likely to discourage inventors from seeking patent protection.
Jeffie A. Kopczynski, Note: A New Era for 112? Exploring Recent	Recent Federal Circuit patent cases have held biotechnology inventions

Developments in the Written Description Requirement as Applied to Biotechnology Inventions, *16 Harv. J. Law & Tech. 229, 230 (2002)*	to a higher written description standard than inventions in other areas, such as the mechanical arts. ... This perception of unpredictability has caused the Federal Circuit to apply a heightened written description requirement to biotechnology patents. This paper argues that the written description requirement for patents should not be applied differently to inventions in different disciplines.
Shraddha A. Upadhyaya, The Postmodern Written Description Requirement: An Analysis of the Application of the Heightened Written Description Requirement to Original Claims, *4 Minn. Intell. Prop. Rev. 65, 120-21 (2002)*	The postmodern trilogy unjustifiably departs from precedent in order to meet the increasing intellectual difficulties of biotechnology patents. The sophisticated obviousness function simply not bar biotechnology patents, but a simple written description requirement will. This anomaly is troublesome. The written description requirement cannot and should not serve any function other than to guarantee that subsequently filed claims are entitled to the benefit of the original application.

Sheila R. Arriola, Biotechnology Patents After Festo: Rethinking The Heightened Enablement and Written Description Requirements, 11 Fed. Circuit B.J. 919, 951 (2002)	The problem created by the Federal Circuit could be remedied by overruling the prior biotechnology enablement and written description case law that heightened these requirements on the basis of the state of technology at the time of those decisions. The USPTO could then relax the enablement and written description requirements with respect to proteins and their analogs. Not only would this shift the determination of patent scope from judges back to the USPTO's biotechnology examiners, but it would force patentees to protect their inventions proactively through continuations and CIPs, rather than reactively through the doctrine of equivalents. On balance, the long-term costs of this proposed approach are far less than those that Festo and the heightened enablement and written description requirements will have on patent protection, and ultimately, on the biotechnology industry as we know it.
Robert A. Hodges, Note: Black Box Biotech Inventions: When a "Mere Wish Or Plan" Should Be Considered an Adequate Description of the Invention, *17 Ga. St. U.L. Rev. 831, 860 (2001)*	The Federal Circuit's imposition of a heightened standard for the written description of DNA inventions in Eli Lilly increases the gap between the written description requirement for biotech inventions and the realities of how such inventions are produced.
Alison E. Cantor, Using the Written Description and Enablement Requirements to Limit Biotechnology Patents, *14 Harv. J. Law & Tech. 267, 313 (2000)*	If courts are strengthening the written description and enablement requirements in order to limit biotechnology patents, this fact raises concerns about creating special standards for particular areas of technology. If it is the courts that impose these standards, pioneering scientists in a new field will be unable to determine, when applying for patents, to what standard their patents will eventually be held when

	they are litigated.
Mark D. Janis, On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines), *2 Wash. U. J.L. & Pol'y 55, 107 (2000)*	As a first step, the Federal Circuit might simply admit that the written description requirement is redundant of enablement. This would at least allow for a more forthright exploration of the question whether redundancy in patent disclosure requirement remains tolerable. The Federal Circuit could reach the conclusion, perhaps, that the written description requirement simply provides a fail-safe mechanism that judges (or examiners) may use in their discretion in hard cases.
Salima Merani, Hyatt v. Boone, *14 Berkeley Tech. L.J. 137, 146 (1999)*	Admittedly, the Federal Circuit has used different expressions in describing a sufficient written description. Judge Newman, however, "[did] not view these various expressions as setting divergent standards for compliance with [section] 112." She emphasized that, in all cases, the purpose of the written description requirement was to ensure that the inventor had possession of the claimed invention at the time of the application filing date. Analysis of historical and policy rationale of section 112 supports Judge Newman's view of the written description requirement.
Zhibin Ren, Note: Confusing Reasoning, Right Result: The Written Description Requirement and Regents of the University Of California v. Eli Lilly & Company, *1999 Wis. L. Rev. 1297, 1324 (1999)*	In Lilly, the Federal Circuit deviated from the well-established traditional written description standard and adopted an ad hoc approach to conduct a written description analysis for DNA claims. This approach allows the court to use whatever is handy to justify the result it wants to reach.
Arti K. Rai, Intellectual Property Rights in Biotechnology: Addressing New Technology, *34 Wake Forest L. Rev. 827, 835 (1999)*	In essence, the Lilly court used the written description requirement as a type of elevated enablement requirement. An ordinary enablement challenge to the University

	of California's claim was not raised (and, if raised, probably would have failed) because it would have been relatively easy for a person of ordinary skill in the art to use the rat insulin cDNA that Lilly had already sequenced to "fish out" the human cDNA from a cDNA library.
Janice M. Mueller, The Evolving Application of the Written Description Requirement to Biotechnological Inventions, *13 Berkeley Tech. L.J. 615, 615-16* (1998)	The Lilly decision may profoundly limit the scope of protection available for new gene inventions;. . . Lilly aptly illustrates the increased widening of the gulf between the norms of the business and scientific communities and the U.S. patent system, as users of the latter come to understand that the patent system no longer reflects the realities of scientific contribution.
Michael Delmas Plimier, Genentech, Inc. v. Novo Nordisk & University of California v. Eli Lilly and Co., *13 Berkeley Tech. L.J. 149, 161 (1998)*	The written description requirement only allows very narrow patents, so narrow and easily dodged as to be almost worthless.
Harris A. Pitlick, The Mutation on the Description Requirement Gene, *80 J. Pat. & Trademark Off. Soc'y 209,* 209-10 (1998)	The recent decision in Regents of the University of California v. Eli Lilly and Co., on top of Fiers v. Revel, decided only a few years before, are such extreme departures from conventional description requirement jurisprudence that the need for new thinking about the issue is now even more manifest. One problem may be nomenclature. As demonstrated later in the text, the term "description requirement" is a misnomer.
Kevin S. Rhoades, The Section 112 "Description Requirement" - A Misbegotten Provision Confirmed, 74 J. Pat. & Trademark Soc'y 869, 869-70 (1992)	[T]here is in fact no justification for carving out a separate "description" requirement from the "enablement" requirement in Section 112, first paragraph, that the specification contain an enabling disclosure of how to make and use the invention. In brief, the language and history of the statute support no such separate requirement, which fulfills no function or purpose not

already
served by the traditional enabling
disclosure
standard.

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Neutrally Commenting on Eli Lilly Written Description

Robert Greene Sterne et al., The Written Description Requirement, *37 Akron L. Rev. 231, 241 (2004)*	It is clear that the written description requirement applies to all technologies covered by patent applications and is not limited to the unpredictable or "complex" arts. The impact of this principle is that the cost and difficulty of drafting patent applications in any art has risen significantly in recent years to adequately protect all variations and permutations of the invention.
Sean A. Passino et al., Written Description Traps For Antibody Claims, *86 J. Pat. & Trademark Off. Soc'y 317,* 318-19 (2004)	To avoid a § 112, first paragraph rejection under the holding of Noelle, an applicant for a U.S. patent may want to disclose a fully characterized antigen if the applicant wants written description support for a claim to an antibody defined by its binding affinity to the antigen. Broader antibody coverage may be obtained by demonstrating the claimed antibody's ability to recognize isoforms of the antigen from one or more different species or by mapping the epitope recognized by the antibody. Furthermore, Noelle has implications wider than § 112, first paragraph rejections. The doctrine may be used against the USPTO, infringers alleging invalidity, and parties of a contested case. Under *35 U.S.C. § 102,* a patent or printed publication will not anticipate a claim unless it "describes" the claimed invention. If the courts take

	the position that a patent or printed publication fails to describe an embodiment for the purposes of § 112, first paragraph, then it is difficult to believe that the same patent or printed publication describes the same embodiment for the purposes of § 102. . . . Clearly, this area of the law is evolving.
Robert M. Schulman, A Review of Significant 2003 Federal Circuit Decisions Affecting Chemical, Pharmaceutical, and Biotech Inventions, 16 No. 3 J. Proprietary Rts. 1, 1 (2004)	In the written description area, 2003 represented the first year in which the court signaled a reversal of the trend it established in 1997, requiring provision of specific sequences for applicants claiming biological molecules. The Federal Circuit is not quite ready to reverse its "written-description-plus" requirement for biotech inventions.
Lewis R. Clayton, Inadequate Descriptions, 4/5/04 Nat'l L.J. 12, col. 1, 12, col. 1+ (2004)	Though the Rochester inventors made, as the district court noted, "significant discoveries in this field," they did not take "the last critical step" of isolating the necessary compound, or "developing a process through which one skilled in the art would be directly led" to it. Absent a reversal en banc, those efforts will not be compensated under the patent laws.
Chandra Garry, Enzo Biochem, Inc. v. Gen-Probe, Inc., *18 Berkeley Tech. L.J. 195, 209 (2003)*	The Federal Circuit in Enzo decided for the first time that the written description requirement may be satisfied by a biological deposit. At first glance, it appears that Enzo lowers the written description standard applied by the court in Lilly, as deposit seems an easy way to satisfy the written description requirement. Any such lowering of the written description

	standard, however, is by and large illusory. The decision in Enzo will likely be strictly limited to its facts. If not limited to its facts, the court's redefined written description is not sufficiently explained by the court so as to provide an easily workable standard for future decisions.
Jeffery M. Duncan et al., Practitioners Be Wary: The Dangers of Functional Descriptions in Biotech Inventions, 15 No. 10 Andrews Ent. Indus. Litig. Rep. 21 (2003)	In the last six years, several patents to biotech inventions that were otherwise valid have been struck down because the description of the invention, often by functional terms, was found wanting. One difficulty for biotech patent practitioners is that there are no bright line rules prescribing what is or is not an adequate written description. Instead, as the U.S. Court of Appeals for the Federal Circuit has repeatedly stated, the satisfaction of the written description requirement is a fact-specific inquiry, decided on a case-by-case basis.
After Determining That a Seller of a Egg Processing Machine May Have Induced Infringement of Patent Claiming a Method Directed High-Speed Egg Processing, the Federal Circuit Address the Written Description Requirement and the Lilly Case Again, 13 Fed. Circuit B.J. 179, 182 (2003)	This case [Moba] highlights the state of flux at the Federal Circuit concerning the written description requirement.
Andrea G. Reister, Enablement & Written Description: Friend or Foe in Litigation?, 766 PLI/Pat 383, 405-6, 409 (2003)	Enzo/Gen-Probe exemplifies the difficulty in annunciating the Federal Circuit's standard for written description, and the dispute within the court over the purpose of the written description requirement and how it relates to the enablement requirement. * * * It remains to be seen whether the Lilly/Enzo/Gen-Probe requirements for

written
description will survive, and supplant the
cases that have dealt with written
description in the context of disputes relating
to priority.

Janet E. Reed et al., Written Description: A Looser Requirement? The Federal Circuit Has Been Edging Away from the Heightened Standard That It Set Out in the 1997 "Lilly' Case, 6/16/03 Nat'l L.J. S1, col. 1, S1, col. 1+ (2003)

In its most recent treatments of the first paragraph of *35 U.S.C. 112*, the U.S. Court of Appeals for the Federal Circuit has edged away from the heightened written
description requirement for biotechnology
patents articulated in Regents of the Univ. of
Calif. v. Eli Lilly & Co., 119 F.3d 1559 (Fed.
Cir. 1997). This process has revealed dissenting opinions among the Federal Circuit
judges, which may only be resolved by en banc
review of the written description requirement
as a whole. As a result, the standard for satisfying the written description requirement remains elusive, leaving practitioners struggling to determine the
level of written description that will be deemed "adequate" to support biotechnology
patent claims.

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Though en banc review of the written description requirement seems timely, the
disparate perspectives of the Federal Circuit
judges make the outcome difficult to predict.
It is uncertain whether a major overhaul of statutory interpretation is in the works,
or whether the current interpretation will
remain substantially intact. The patent bar
and the biotechnology industry will no doubt
eagerly await resolution of the current ambiguity, accompanied, it is to be hoped, by
pronouncement of a clear standard for

	written description to be applied by the PTO during patent prosecution and by the courts in patent litigation.
Mary S. Consalvi, The Enablement and Written Description Requirements, 766 PLI/Pat 349, 377, 381 (2003)	With this decision [Enzo Biochem] and the decision in Amgen Inc. v. Hoeschst *Marion Roussel, 314 F.3d 1313* (Fed. Cir. 2003), it is clear that written description is still in a state of uncertainty and ambiguity. * * * The law of enablement and written description under *35 U.S.C. § 112*, first paragraph is constantly evolving and emerging. At the present time, there is still a lot of uncertainty in the area.
Anne Y. Brody, Ph.D., Rochester v. Searle: Complying with the Written Description and Enablement Requirements in Early-Stage Drug Discovery, 22 Biotechnology L. L. Rep. 472, 474 (2003)	This case touches on many uncharted areas of biotechnology patent law. With the emerging fields of genomics and proteomics, the law has to keep up with biotechnological advances. In the University of Rochester's pending appeal to the CAFC, the real issue for the written description requirement may depend on where in the time line of research and development a discovery turns into an invention. Is such a method of treatment claim valid only when a selected group of compounds is identified? Or are the solutions (e.g., the drug compounds and their screening methods) obvious once the source of the problem is determined? The determinative factor in the enablement requirement may be contingent on the definition of "undue experimentation" in the field of drug development. The amount of guidance and what is undue experimentation change as technologies progress to standardize many

	laboratory techniques. For example, in recent years, high-throughput screening technologies have reduced time and effort scientists expend to conduct numerous parallel experiments simultaneously. Selecting a starting material and creating a pool of its variants for screening are now conventional procedures among the researchers in biotechnology.
Todd M. Oberdick, Section 112, Paragraph 6 - Means Claim and Limitation to Specific Algorithm - Is This a Stricter Standard Than Gentry Gallery and Related Mechanical Cases?, *22 Pace L. Rev. 385, 390 (2002)*	In light of Gentry Gallery and Johnson Worldwide, a patent practitioner may be tempted to omit a precise description of a preferred embodiment of the invention for fear of making "crystal clear" that a narrow claim interpretation was intended.
Lisa A. Karczewski, Comment: Biotechnological Gene Patent Applications The Implications of the USPTO Written Description Requirement Guidelines on the Biotechnology Industry, *31 McGeorge L. Rev. 1043, 1086 (2000)*	The Federal Circuit's trilogy of landmark biotech decisions in the past decade have made an obvious mark with respect to the future of obtaining patent protection for genetically engineered products and the specificity required for satisfying the written description requirement. Having incorporated the reasoning from these decisions into the methodology of its guidelines, only time will tell whether the USPTO's efforts will impede the patent application process for the biotechnology industry.
Scott A. Chambers, "Written Description" and Patent Examination Under the US Patent and Trademark Office Guidelines, IP Litigator 9, 9 (Sept./Oct. 2000)	While some practitioners and the Patent and Trademark Office (PTO) cannot ignore the law as interpreted by the Court of Appeals for the Federal Circuit and must respond in a manner that continues to protect the intellectual property interests of their clients. Moreover, the Federal Circuit's clarification of the written description requirement suggests that some broadly drawn patents may be vulnerable to attack for

	lack of written description.
Cindy I. Liu, Gentry Gallery, Inc. v. Berkline Corp., *14 Berkeley Tech. L.J. 123, 123* (1999)	In Gentry Gallery, Inc. v. Berkline Corp., the Federal Circuit narrowed the scope of patents through the written description requirement of section 112 by announcing an omitted element test.
Laurence H. Pretty, The Recline and Fall of Mechanical Genus Claim Scope Under "Written Description" in the Sofa Case, *80 J. Pat. & Trademark Off. Soc'y 469,* 479-80 (1998)	It remains to be seen whether Gentry Gallery will become a more influential precedent than Utter v. Hiraga in permitting attack upon a genus claim in the predictable arts by limiting patent protection to the species disclosed. . . . It may also be advisable to include a claim of extreme breadth as the first filed original claim even at the risk of presenting a claim that is highly likely to be rejected, in order to negate any inference that "written description" will bar any broader claim later.

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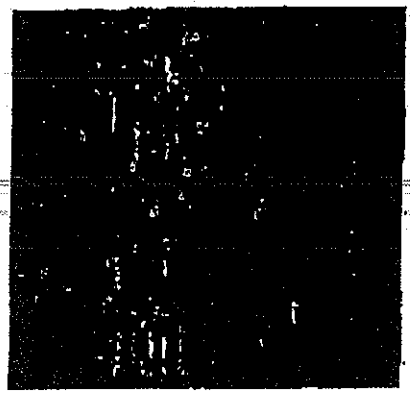
Economist 12/14/02

Innovation's golden goose



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The reforms that unleashed American innovation in the 1980s, and were emulated widely around the world, are under attack at home

REMEMBER the technological malaise that befell America in the late 1970s? Japan was busy snuffing out Pittsburgh's steel mills, driving Detroit off the road, and beginning its assault on Silicon Valley. Only a decade later, things were very different. Japanese industry was in retreat. An exhausted Soviet empire threw in the towel. Europe sat up and started investing heavily in America. Why the sudden reversal of fortunes? Across America, there had been a flowering of innovation unlike anything seen before.

Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.

Before Bayh-Dole, the fruits of research supported by government agencies had belonged strictly to the federal government. Nobody could exploit such research without tedious negotiations with the federal agency concerned. Worse, companies found it nigh impossible to acquire exclusive rights to a government-owned patent. And without that, few firms were willing to invest millions more of their own money to turn a raw research idea into a marketable product.

The result was that inventions and discoveries made in American universities, teaching hospitals, national laboratories and non-profit institutions sat in warehouses gathering dust. Of the 28,000 patents that the American government owned in 1980, fewer than 5% had been licensed to industry. Although taxpayers were footing the bill for 60% of all academic research, they were getting hardly anything in return.

The Bayh-Dole act did two big things at a stroke. It transferred ownership of an invention or discovery from the government agency that had helped to pay for it to the academic institution that had carried out the actual research. And it ensured that the researchers involved got a piece of the action.

Overnight, universities across America became hotbeds of innovation, as entrepreneurial professors took their inventions (and graduate students) off campus to set up companies of their own. Since 1980, American universities have witnessed a tenfold increase in the patents they generate, spun off more than 2,200 firms to exploit research done in their labs, created 260,000 jobs in the process, and now contribute $40 billion annually to the American economy. Having seen the results, America's trading partners have been quick to follow suit. Odd, then, that the Bayh-Dole act should now be under such attack in America.

No free lunch

There has always been a fringe that felt it was immoral for the government to privatise the crown jewels of academic research. Why, they ask, should taxpayers be charged for goods based on inventions they have already paid for?

That is easily answered. Invention, as TQ has stressed before, is in many ways the easy bit. A dollar's worth of academic invention or discovery requires upwards of $10,000 of private capital to bring to market. Far from getting a free lunch, companies that license ideas from universities wind up paying over 99% of the innovation's final cost.

Then there is the American Bar Association, which has lobbied hard to get the government's "march-in" rights repealed. The government has kept (though rarely used) the right to withdraw a licence if a company fails to commercialise an invention within a reasonable period. This was to prevent companies from licensing academic know-how merely to block rival firms from doing so. The lawyers argue that the government could use its walk-in rights to bully pharmaceutical firms into lowering the price of certain drugs.

Whatever the merits of their case, suffice it to say that the sole purpose of the Bayh-Dole legislation was to provide incentives for academic researchers to exploit their ideas. The culture of competitiveness created in the process explains why America is, once again, pre-eminent in technology. A goose that lays such golden eggs needs nurturing, protecting and even cloning, not plucking for the pot. Readers who agree or disagree can share their own views at www.economist.com/forums/tq.

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Robert J. Samuelson

WASH. POST 9/22/04

Prognosis: Stalemate

Our health care system is a frustrating mix of routine miracles and scandalous failures. The miracles abound; Bill Clinton's recent open-heart surgery was cutting-edge a few decades ago. Failures also abound. In 2003, 45 million Americans lacked health insurance, and medical spending spiraled furiously upward. Since 2000 private insurance premiums have increased 59 percent, reports the Kaiser Family Foundation. Both George Bush and John Kerry say they'll "fix" the health care system, but their campaign proposals suggest that neither is serious.

To be serious would require admitting that the basic problem does not lie with insurance companies, trial lawyers, hospitals or any of the usual suspects. It lies with public opinion. We Americans want the impossible. We want our health care system to provide everyone with good care covered by comprehensive insurance, prevent insurance companies or government bureaucrats from dictating our choice of doctors, hospitals or treatments, and hold down costs. Well, we can have any two of these goals—but not all three. If everyone has coverage and choice, costs will skyrocket. No one is empowered to control them. But controlling costs involves limits on insurance or choice.

Consider managed care as a case study. It expanded in the 1990s and, by limiting choice, restrained costs. From 1994 to 1998, per capita health care spending rose only 3 percent annually. "There were a lot of controls. You needed permission for admission to hospitals or to get an MRI," says Paul Ginsburg of the Center for Studying Health System Change. Doctors and patients revolted against restrictions that seemed wrong. Managed care relaxed. Per capita spending surged; increases were 10 percent in 2001, 9.5 percent in 2002 and 7.4 percent in 2003.

Not wanting to offend voters, both Bush and Kerry ignore conflicting goals.

Kerry's approach is to throw money. If you spend enough, you can insure many uninsured. He would expand Medicaid and the State Children's Health Insurance Program. Children of families with incomes less than three times the poverty line, or about $56,000 for a family of four, would become eligible. Kerry would provide tax credits for small businesses that offered insurance. The federal government would also subsidize the insurance of big employers; his plan would pay 75 percent of catastrophic health spending for individuals over some limit, beginning at $30,000 and rising annually.

If enacted, Kerry's plan would extend insurance to 27 million people, according to separate estimates by Kenneth Thorpe of Emory University and a team headed by Joseph Antos of the American Enterprise Institute. The cost is unclear. Thorpe puts it at $653 billion from 2005 to 2014; the Antos group estimates $1.5 trillion from 2006 to 2015. Either way, Kerry's plan is expensive. The fact that he would finance it by repealing Bush's tax cuts for those with incomes over $200,000 doesn't change that.

Bush's plan costs less—and does less. The White House says its plan would insure "more than 11 million and as many as 17.5 million" Americans. Antos's team figures 6.7 million and estimates the cost at $129 billion from 2006 to 2015. The president proposes tax breaks for health savings accounts (HSAs). Tax-deductible contributions to these accounts can be used for ordinary health expenses. People with HSAs are also required to have catastrophic insurance coverage for medical emergencies. The idea is to promote cost-consciousness for routine spending, while making insurance—covering only big bills—more affordable. Despite rhetorical boasts, neither plan would control health spending.

Kerry claims to make health insurance more affordable. Technically, this is true. But he merely shifts health costs from private companies and workers to the federal budget and taxpayers. Because health care spending is hard to control, this would make future budgets less manageable. In 2003 health costs accounted for 23 percent of federal spending, up from 7 percent in 1970. With current policy, that reaches 29 percent in 2014, projects the Congressional Budget Office. Under Kerry, it would go higher.

Bush says his plan "will help reduce the rising cost of health care." Just how is unclear. Even if HSAs unexpectedly exploded, the resulting cost-consciousness would affect only a small part of spending. About 10 percent of patients—the very sickest—account for 70 percent of spending, says health economist Len Nichols. HSAs don't touch these costs. Limiting malpractice suits (a Bush goal) wouldn't help much; savings might total two-tenths of one percent of spending, estimates the Lewin Group.

What unites Bush and Kerry is an unwillingness to challenge public opinion. People blame high health costs on "waste" or excessive profits. These convenient explanations are exaggerated. In 2003 the profits of health maintenance organizations totaled $10.2 billion, reports Weiss Ratings Inc. They represent a small percentage of the $1.6 trillion spent for health care. The real causes of higher spending are stubborn: We're an aging society; science creates new drugs, diagnostics and treatments; people want the latest and best—at someone else's expense.

Our medical advances save lives and improve the quality of life. But some spending—perhaps a lot—is unneeded. The practical problem, says Drew Altman of the Kaiser Family Foundation, is to find ways of imposing limits on individual patients. This is hard at best, but it requires a political will that's missing. Bush and Kerry won't tell voters what they don't want to hear, even if unchecked health spending puts pressure on wages, other government programs or taxes. Regardless of who wins, the prognosis is for more of the same.

Dear Colleagues

~~I would like to~~ Pardon my interruption of ~~put aside for a moment the~~ your on going discussions ~~of compulsory licensing~~, I would like to say a few words about ~~Ronald~~ Pres. Reagan.

From the beginning the Reagan White House embraced Bayh-Dole with open arms. It fit exactly into the Reagan agenda of deregulation and decentralization of decision making ~~to those~~ closest and incentive for inventors and innovation. ~~with the hope~~ The White House was actively involved in enhancing the Act's incentives and implementation as part of their effort. OMB Circular A-124 implementing the Act was issued in 1981 over the resistance of agency bureaucracies. ~~[illegible]~~ his 1983 Executive Memo expanded the Act to additional contractors ~~[illegible]~~ the 1984 amendments and their 1987 implementing regulations expanded the incentives for participation in invention and ~~technology transfer~~ ~~[illegible] the executive~~ the 1987 FTTA extended the prerogatives of the non-profit organizations to the Federal Laboratories. This completed the Bayh-Dole body of laws, regulations and Executive Actions that are ~~function under~~ now your legacy.

Pres. Reagan will also be remembered for ending the cold war. Decades ~~[illegible]~~ from now historians will realize the amazing contribution

Pres. Reagan frequently ~~[illegible]~~ reminded us that the Soviet Union would ultimately fail because it suppressed the major incentives for innovation, inventions & entrepreneurship,

In our country ~~[illegible]~~ entrepreneurship, to [illegible]

his 1987 executive order restated and emphasized all of these executive actions

Reagan the White House made to the rebirth of innovation

Yes, America Has a 'New Economy': Technology

Global View

By George Melloan

Federal Reserve Chairman Alan Greenspan gave unexpected support to "New Economy" theorists in a speech at the Gerald R. Ford Foundation in Grand Rapids 13 days ago. Information technology, he said, "has begun to alter, fundamentally, the manner in which we do business and create economic value." By enabling businesses to remove "large swaths of unnecessary inventory," real-time information is accelerating productivity growth and raising living standards. This has contributed to the "greatest prosperity the world has ever witnessed."

That is bullish talk for a man better known for chiding Wall Street for its "irrational exuberance," long before the Dow soared above 11,000. There can be little doubt, however, that there is a new, technology-based economy roaring toward the year 2000 and that Americans are its primary driving force. So it is fascinating to contemplate what new technological marvels we're likely to see in the 21st century. Just as engaging is reflection on why it is that the U.S. has become the fountainhead of creativity in science and engineering. A lot of other nations would like to find the secret and bottle it.

But first a look at some of the hot technologies, some gleaned from a bibliography prepared by the Organization for Economic Cooperation and Development in Paris. OECD researchers expect further dramatic advances in information technology, with desktop computers heading onward and upward in memory and speed. Gene-replacement therapy could be widespread by 2025, as the Human Genome Project unlocks further mysteries of the human body.

Meanwhile, Rand Corp's Critical Technologies Institute, surveying corporate executives, forecasts that over the next 20 years "molecular medicine" will lead to powerful medications and therapies that treat diseases at the genetic level. Therapy will be applied at earlier stages of disease and will be adapted to individual patients. These more precise treatments will further advance life expectancies.

"The same deeper understanding of genetics that is poised to revolutionize health care and its attendant industries also offers the potential for more precisely breeding plants and animals," says the Rand survey. "Depending on consumer acceptance, by the early part of the next century, much of the world's produce may be genetically engineered in some way."

Materials technology is a wide-open field, with possibilities for flexible glass or ceramics and, most fascinating, the marriage of biology and engineering to produce combinations of organic and inorganic materials that are, in effect, self-assembling. Tiny sensors will someday eliminate the need for highway toll booths and regulate automobile engines, in both cases saving enormous amounts of fuel. Imaging technology is progressing toward identifying tinier objects, advancing molecular medicine and genetic engineering.

In transportation, look for the "hybrid car" early in the 21st century, using fuel cells, an advanced electrical battery. "Over the longer term, fuel cells, combined with super-strong, ultra-light polymers or ceramics, could provide true energy savings for the transportation sector," the Rand study says.

The reason the U.S. is leading the technological revolution is partly its great wealth. Its corporations, universities and national laboratories are the world's leading spenders on research and development, with outlays double the nearest rival, Japan. But there is a lot more to this great burst of creativity than just the amount of money spent. Far more important is the environment that Americans have created—or perhaps preserved is a better description—that fosters and rewards creative effort.

The Bayh-Dole Act of 1980 allows recipients of government grants to retain title to their inventions. Says a study on basic research by the Committee for Economic Development: "This law has stimulated intense growth in university patenting and a subsequent technology transfer from basic research institutions to industry. As a result, industry is increasingly involved in collaboration with, and sponsorship of, university-based researchers." For example, the CED report notes that there are 1,000 companies in Massachusetts with relationships with the Massachusetts Institute of Technology. Their worldwide sales are $53 billion. "Similar developments have taken place in California's Silicon Valley and the Research Triangle of North Carolina."

Genetics research will revolutionize health care.

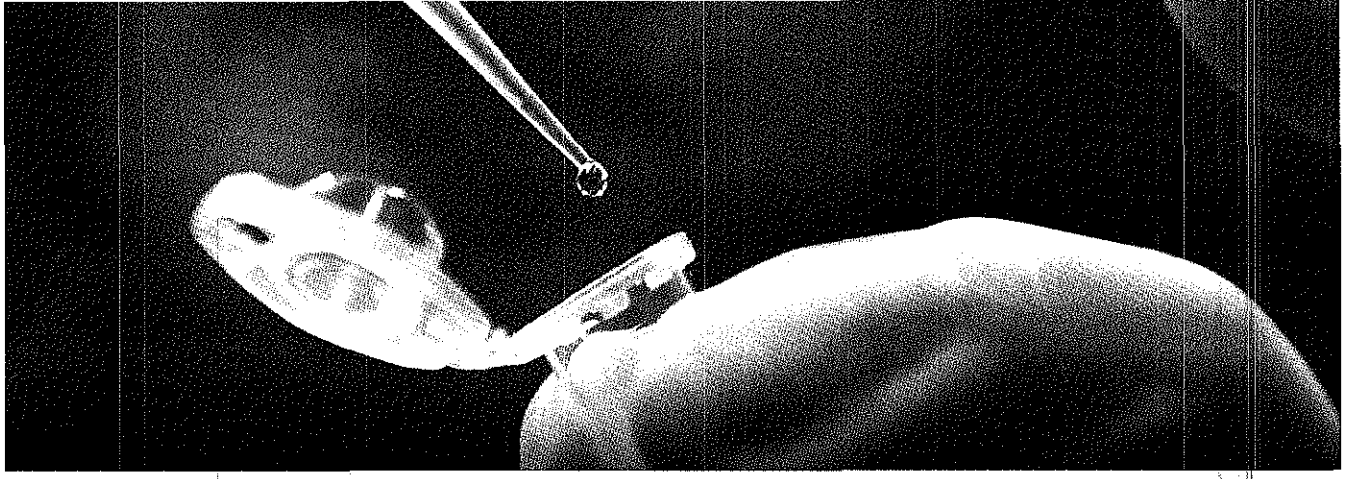
But many places elsewhere in the world are lacking one or more of the magic ingredients that have made the U.S. the great dynamo of the technological revolution. No country, for example, can match America's vast network of colleges and universities, teaching hospitals and private-research institutions, not to mention the labs of its multinational corporations. These centers of research attract aspiring scientists and engineers from all over the world and many find the intellectual climate so much to their liking that they settle permanently in the U.S.

U.S. national laboratories, though suffering from the usual inefficiencies of tax-supported institutions, nonetheless direct grants to thousands of individuals who are pursuing promising lines of research. And the ease with which individuals can start businesses in the U.S., in sharp contrast to Europe and Asia, means that good ideas spawn new firms, which often grow large and provide shelter and stimulation for new generations bent on making their marks in research and development.

But there is more to it than that. The U.S. would never have arrived at this stage without the changes in the public policy environment that have transpired over the last 20 years. Ronald Reagan set in motion a deregulatory and tax reform process that has survived to this day. Efforts by the Clintons to nationalize the health industry, which surely would have stultified medical research, failed. So did the effort of Vice President Al Gore to whip up "environmental" hysteria and thus expand the regulatory burden, which is a particular curse for small start-up firms, at a faster rate.

Another Rand study comparing the U.S. with the European Union, Japan, China and South Korea shows that the U.S. leads in providing a climate of openness to foreign trade and investment. This helps make the U.S. economy highly competitive. Competition stimulates innovation. That is reflected in Rand statistics showing that American industry sharply expanded its employment of Ph.D. scientists and engineers between the years 1973 and 1991, increasing its share, relative to other employers, to 36% from 24%.

There are lessons in all this. All this new science didn't just happen. It had to be incubated. If the U.S. can preserve the environment that hatches inventions, it can look forward with optimism to the 21st century. Present evidence suggests that the 21st may even outstrip the 20th as a century of science.



Developing new pharmaceuticals takes time. That's why it is important to protect products with various additional patents.

AWA Information No. 2. 2004

Risk analysis – more than just patents

The venture capitalist. A person with cash, contacts – and the power to shape the future of a company. But what does he look for when evaluating an investment opportunity?

Venture capital company Investor Growth Capital AB (IGC) invests in small private companies in the life science and information technology sectors. By controlling between 10 and 49 percent of the share capital in a company IGC can exert an influence – at board level, for example – without tying up more capital than necessary.

"So far we've invested in around 25 life science companies," says Staffan Josephson. "Our ambition is to assume an active role for five to seven years, and that means contributing more than just money. We have a fantastic network of contacts. That's an added strength we can bring to the board."

Professor of Organic Chemistry and former research chief at Pharmacia in Stockholm, Staffan Josephson is now responsible for evaluating investment potential and product ideas within life science for IGC.

"I'm the first hurdle," he says. "If I see potential in a company, we carry out a quick, superficial due diligence. If the prospect still seems appealing, we then take a closer look, identifying co-financiers and engaging in a dialogue with the company over a period of several weeks."

Is this when the focus shifts to patent issues?

"Yes – that's when patents become the single most important factor. Experience has taught us that, without sound patent protection, there is rarely anything of value. The cost of development, in time and money, is so great you can't afford to have everything blow up in your face at the end of an investment, when you're selling the company or the product. That's why we employ consultants to help us evaluate the companies' patent strategies."

> "Development costs are so high you can't afford to have everything blow up in your face at the end of an investment, when you're selling the company or the product."

What do you look at?

"We try to identify the need for getting licences for patents in areas where a company's work overlaps that of others. Seeing this early on – before the seller realises why – dramatically reduces licensing costs.

"We also focus on the protection afforded to the main patent, further developments and the scope for additional patents. The pharmaceuticals industry has learned that, for every year you can prolong your sole rights in the market, the effect is enormous in dissuading generics from targeting your market share."

So the experiences of the pharmaceuticals industry affect your risk analyses?

"To some extent. We seldom follow products all the way to market, so we have to know that the patent protection is strong enough to survive the beady eyes of the pharmaceutical industry."

Do you believe that strategic development potential has become more important?

"Yes. Life science is a young market, but we've already learned what to look for. In the late 90s we would go in at a very early stage. Now we look more closely at strategic aspects, what the future holds in store, what else can be protected and what kind of related potential there is. This kind of risk analysis can not be more important that what it has already become." ■

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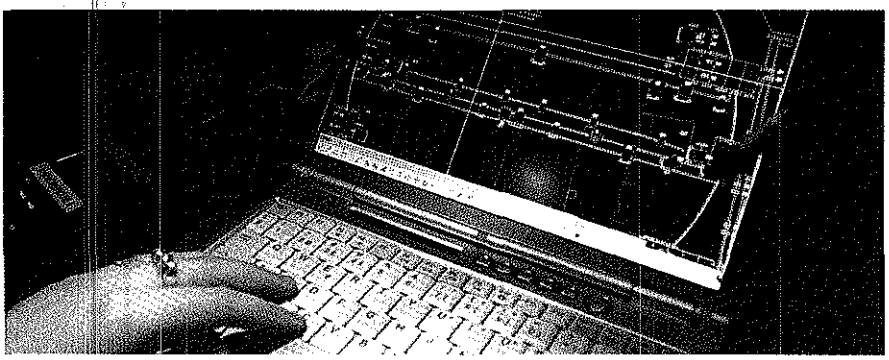
FACTFILE

THE OLYMPIC GAMES – A MARKETING HISTORY

1896 Athens. Wealthy benefactor pays for the stadium. Adverts in the programme.
1912 Stockholm. Around a dozen companies buy photo rights: one sets up scales for people to weigh themselves on.
1924 Paris. The one and only time that advertising is permitted in the arena.
1928 Amsterdam. Coca-Cola starts a tradition of sponsorship that continues to this day.
1936 Berlin. The first Olympic television broadcasts are seen by around 162,000 viewers.
1948 London. The BBC pays for the television rights, but the cheque is never cashed because of the BBC's financial difficulties.
1964 Tokyo. The Olympia cigarette company pays $1 million for rights, but is later banned.
1972 Munich. The first mascot, Waldi, is licensed for sale to the public.
1984 Los Angeles. Sponsorship enters a new era. 2.5 billion viewers watch the Olympic Games on television.
2000 Sydney. $3 billion in marketing revenue.



Undercover action against pirates

More people are copying products that are legally protected by copyright, such as games and films, etc., via the internet.

Just how widespread this copyright piracy is, no one can say for sure. But the fact that 80–90 percent of what is transmitted via broadband is copyrighted material provides some indication of the extent of the problem.

So what is the industry doing to thwart the pirates? Few know more about that than Henrik Pontén, a representative of the Swedish anti-piracy organisation, *Svenska Antipiratbyrån*.

"The methods we use would be completely ineffective if they became known. Generally you could say that we run various projects to disrupt file-sharing programs. The weakness with these programs is that nobody takes responsibility for their quality. That makes them extremely vulnerable to attack."

What this means in concrete terms is something Henrik is reluctant to expand on. What deters people from downloading files, however, is when they end up downloading the wrong things.

"There are lots of ways to do this. One common method is 'spoofing'. This involves flooding the net with empty files named after a popular film, a piece of music or a game. If someone downloads a file ten times and gets the wrong content every time, perhaps their enthusiasm for pirated copies will wane…"

Another method is to track down the people trading films and computer games, obtain documentary proof of their illegal activities, and then contact them.

"In Sweden we send them a warning letter and inform them of the law. In Denmark people who have downloaded files are sent an invoice, while in the USA legal measures are taken."

However, the real showdown has only just begun.

"A few years from now, we will be laughing at this discussion. Either we will have won the war against the pirates, or we will have lost – in which case there won't be any industry left to defend. But I'm convinced that the film and computer game industries will invest the resources needed to tackle this problem," Henrik concludes. ■

News items

■■■

Castro's cigar saved
Cuba's Cubatabaco has been granted trademark protection in the USA for its world famous Cohiba cigar. A US federal court ruling has prevented New York-based General Cigar from selling its own version of the Cohiba, although General Cigar intends to appeal against the decision.

The original Cohiba, developed in the late 1960s by Fidel Castro's personal cigar roller, has become the most internationally coveted of all Havana cigars.

■■■

Disney triumphs in Pooh Wars
After a thirteen-year legal battle between the Slesinger family and Disney over royalties for the Winnie the Pooh character, a Los Angeles court has finally ruled in Walt Disney's favour.

The Stephen Slesinger company bought the sales rights to the simple-minded bear from the bear's creator A.A.Milne in 1930. The dispute began in 1991 when Slesinger's heirs sued Disney for failing to pay royalties on the sale of Winnie the Pooh dolls, books and other merchandise.

■■■

Belgium signs up for Locarno
With effect from 23 June Belgium will become an official signatory to the Locarno Agreement, which establishes an international classification for the registration of industrial designs. This brings the number of countries that have ratified the agreement to 44.