No. 08-964

In The Supreme Court of The United States

BERNARD L. BILSKI AND RAND A. WARSAW,
Petitioners,

v.

DAVID KAPPOS, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR, PATENT AND TRADEMARK OFFICE,
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* KNOWLEDGE ECOLOGY INTERNATIONAL IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICUS CURIAE*[1]

Knowledge Ecology International (KEI) is a not for profit non governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources, as is described in http://www.keionline.org. KEI is particularly concerned with areas where current business models and practices by businesses, governments or other actors fail to address social needs, and where there are opportunities for sustainable improvements. KEI is, in the strictest sense, a broad-based IP policy research organization, as opposed to some of the more narrowly focused special-interest *amici* that have already submitted briefs. KEI has no financial interest in the outcome of this case.

KEI submits this brief because it is concerned that the Court will gain only a limited perspective from those parties, instead of the long-term view of the consequences of this case necessary to fashion an appropriate remedy. Because the very nature of intellectual property and the Constitutional clause itself, which focuses on the long- instead of the short-term, this case can only be decided appropriately if the entirety of the intellectual property regime is considered as opposed to the particular interests of more narrowly-focused corporate players.

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1 Letters of the Parties' general consent to file *amicus* briefs are on file with the Court. This brief was not authored in whole or in part by counsel for any party. No one other than *Amici* and their counsel made a monetary contribution to preparing or submitting this brief.

KEI is an advocate of new incentive and financing models for biomedical innovation and has proposed various mechanisms for stimulating investments and promoting innovation, such as the use of innovation inducement prizes, competitive intermediaries and open source dividends to reward successful investments in medical research and development. Depending upon the context, these approaches function either as alternatives or complements to the grant of a patent monopoly, in the context of a larger environment of systems that support innovation. KEI has an interest in ensuring that the Supreme Court guides patent law in a way that does not stifle innovation, simultaneously respecting the interests of patients and protecting the future of science.

ARGUMENT

THE GOAL OF THE PATENT REGIME IS NOT TO REWARD INVENTORS, BUT TO ENCOURAGE PROGRESS

As this Court has repeatedly admonished, the goal of the intellectual property regime is to promote progress, not to reward individual authors or inventors. This Court has often noted that the inventor is incidental to the patent system, the goal of which is not the inventor's fortuitous monopoly but the invention's overall contribution to the public domain. See *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 349 (1991) ("The primary objective of copyright is not to reward the labor of authors, but 'to promote the Progress of Science and useful

Arts.'") (alteration in original) (citation omitted); *United States v. Paramount Pictures, Inc.,* 334 U.S. 131, 158 (1948) ("The copyright law, like the patent statutes, makes reward to the owner a secondary consideration."); *United States v. Line Material Co.*, 333 U.S. 287, 320 (1948) ("But however that may be, the Constitution places the rewards to inventors in a secondary role. It makes the public interest the primary concern in the patent system."); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917) ("This court has consistently held that the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is 'to promote the progress of science and useful arts ... .'") (citation omitted); *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 327-28 (1858) ("It is undeniably true, that the limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly."); *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 11, 18 (1829) ("While one great object was, by holding out a reasonable reward to inventors, and giving them an exclusive right to their inventions for a limited period, to stimulate the efforts of genius; the main object was 'to promote the progress of science and useful arts ... .'") (citation omitted).

In the short-term, of course, innovators, and their commercial representatives, strongly desire the economic profits guaranteed by the patent monopoly. But those desirable profits are secondary to the long-

term goals of the patent system, which are not to reward innovators, but to assure progress. By definition, therefore, in some areas of innovation, outside the scope of the patent regime, progress will be assured by means other than the patent system. It is not the duty of this Court or of this case, to fashion a test tailored to the needs of industries, which may be outside the scope of what the Framers intended when they limited patents to the "useful arts" as opposed to all of science, and as well, only to inventors, and not all innovators. Such a shortsighted approach, urged on this Court by some of the parties and *amici* may well retard progress, especially in certain areas of medical innovations where the costs of patent system are higher than the benefits, or where alternative methods of rewarding successful innovation achieve superior results.

IN CASES WHERE INAPPROPRIATE GRANTING OF PATENT PROTECTION HINDERS PROGRESS IN THE ARTS AND SCIENCES, IT IS NOT NECESSARY TO FASHION AN OVERLY BROAD DEFINITION OF PATENT SUBJECT MATTER MERELY TO SAVE MEDICAL INNOVATIONS FROM AN IMAGINED AND SPECULATIVE DANGER

The argument that this case requires a broad definition to encourage medical innovation puts the cart before the horse. The patent monopoly is designed to promote the "useful arts," not all of science. The task here is to determine a test that will exclude those areas of economic and research activity that were never intended or should not now

be a part of the patent regime. It is therefore relevant to note that certain medical innovations were never thought to be a part of the patent regime until very late in the two hundred year history of our nation. For many years after *Morton v. New York Eye Infirmary*, 17 F. Cas. 879 (C.C.S.D.N.Y. 1862), it was assumed "that medical and surgical methods of treating the human body were not patentable processes."[2]

The petitioner as well as some *amici* has argued here that a broad definition of patent eligibility is necessary in order to stimulate investment in the research and development of new products. Some urge that the "machine-or-transformation" test will wreak "havoc" on the biotech industry. (*See, e.g.,* Br. of *Amicus Curiae* of Biotechnology Industry Organization, et al. at 15) Some misread *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) to say that it bars any non-statutory exclusions from patent subject matter (*See, e.g.,* Br. of *Amicus Curiae* Novartis Corporation at 10). Others insist that what are basically savings clauses in Section 287 (a remedies section) are somehow broad assertions of patent scope, which, as remedies provisions, they obviously are not (*See, e.g.,* Br. of *Amicus Curiae* of Georgia Biomedical Partnership, Inc. at 16). Still others insist that anything but the broadest, and possibly improperly broad, test of patentable subject matter would render personalized medicine impossible, ignoring all the myriad other non-patent mechanisms available to stimulate innovation in this

2 *Chisum on Patents.* §1.03.

area (as well as the fact that medical practitioners already enjoy immunity from patent infringement liability in many cases making those medical patents far less effective at encouraging innovation) (*See, e.g.,* Br. of *Amicus Curiae* of Medtronic, Inc). Still others urge that this Court make special, especially strained, rules of an almost *sui generis* nature in order to protect particular enterprises (*See, e.g.,* Br. of *Amicus Curiae* of Pharmaceutical Research and Manufacturers of America).

Common to each of those arguments is the unstated assertion that patent protection is a necessary policy intervention to reward successful investment in new medical technologies, and the argument that the failure to do so will have severe consequences for innovation.

While it is certainly true that the granting of patents on new medical technologies or discoveries will in some cases provide incentives for such investments, it is also certainly true that the granting of monopolies on discoveries or inventions, and especially innovations outside of the scope of the Constitutional Clause, however defined, presents costs to society, both in terms of high prices for products and also in terms of the restrictions on innovation by others. The design of patent policy by the Congress or the Courts is constrained and informed by this tension. As noted above, the patent regime is constrained by a Constitutional mandate to promote "progress," as opposed to rewarding particular sectors or innovations indiscriminately, including those that are better encouraged through

the non-patent mechanisms. It should be noted, also, that many of the greatest medical advances have benefited significantly, and in some cases exclusively, from mechanisms that exist completely outside of the patent system.

Finally, there is very little support for the proposition that the scope of the Patent Statute is, effectively, unlimited. For instance, those who rely on *Diamond v. Chakrabarty* for the proposition that there are no common law limits on the scope of patent subject matter simply misread that case. The Federal Circuit has purported to understand that decision to mean that it is improper for courts to read judicial exceptions into the Patent Act. *State Street Bank & Trust Co. v. Signature Financial Group, Inc,* 149 F.3d 1368. (Fed. Cir. 1998). But in the same breath, the Federal Circuit recognizes exceptions for "laws of nature, natural phenomena, and abstract ideas," even though those are not statutory, but judicial limits derived from *Diamond v. Diehr*, 450 U.S. 175 (1981).

NON-PATENT MECHANISMS CAN, AND ARE SUPPOSED TO, ENCOURAGE PROGRESS IN AREAS WHERE THE GRANT OF A PATENT IS INSUFFICIENT, INEFFECTIVE, BURDENSOME, IRRELEVANT OR UNNECESSARY

A. A host of non-patent mechanisms are already used to encourage research.

The life sciences, as well as other areas of technology

and commerce, are not dependent upon patents *per se* to stimulate investments. Policy makers have created a wide variety of mechanisms to protect, reward and induce investments in medical, agricultural, computer, software and other areas of innovation.

One policy intervention that is common to all areas concerns trade secret protection, which is enforced both through contracts and civil litigation, and in criminal statutes.[3] See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974). The role of trade secrets in protecting medical products is particularly important in the areas of medical diagnostic technologies, and biotechnology drugs.[4] As explained below, new medicines and vaccines are also protected by a plethora of *sui generis* intellectual property regimes that do not depend upon evidence of invention.

One important non-patent mechanism is the Orphan Drug Act[5] which provides for seven years of exclusive rights to sell a medicine, for certain ailments.[6] In addition to the seven-year period of exclusive rights, the Orphan Drug Act offers a

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3 THEFT OF TRADE SECRETS, 18 U.S.C. § 1832; ECONOMIC ESPIONAGE, 18 U.S.C. § 1831.

4 Iraj Daizadeh et al., *A general approach for determining when to patent, publish, or protect information as a trade secret*, 20 NAT BIOTECH 1053-1054 (2002).

5 PROTECTION FOR DRUGS FOR RARE DISEASES OR CONDITIONS, 21 U.S.C. § 360CC.

6 Marlene Haffner, *Adopting Orphan Drugs -- Two Dozen Years of Treating Rare Diseases*, 354 NEW ENGLAND JOURNAL OF MEDICINE (2006).

system of grants and tax subsidies for the development of such products. Most importantly, the Orphan Drug Tax Credit allows investors to recoup 50 percent of qualified research and development expenditures in the form of lower taxes on income from other products.[7]

A separate form of exclusive rights concerns test data used to register new medicines with the Food and Drug Administration. Before a new drug is introduced into the market, evidence of its safety, effectiveness and quality must be provided to the national drug regulatory authorities. Such evidence includes data from clinical trials involving humans, the most expensive element of drug development. Originators of products receive a time-limited monopoly to rely upon the evidence given to a regulatory body. After this time-limited monopoly expires, a generic drug company may rely on the test data submitted by others.[8] There are many economic, practical and ethical reasons why a generic entrant into the pharmaceutical market will not attempt to reproduce the test data. The tests are expensive, often take several years to complete, and the replication of the trials will in important cases violate ethical rules against repeating experiments on humans.[9] These protections are so strong that

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7 Clinical testing expenses for certain drugs for rare diseases or conditions, 26 U.S.C. § 45C.

8 DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984, 21 U.S.C. § 355 ET SEQ.

9 Judit Rius Sanjuan, James Love & Robert Weissman, *Protection of Pharmaceutical Test Data: A Policy Proposal*, KEI RESEARCH PAPER 2006:1.

they prevented any generic competition for the unpatented blockbuster cancer drug Taxol, until the FDA data exclusivity period expired.[10] Like the Orphan Drug Act exclusivity discussed above, these rights are not tied to inventive activity, and reward investment in product development completely outside of the patent regime.

There are regulatory monopolies associated with investments in the testing of medicines on children. Under Section 505A of the Federal Food, Drug, and Cosmetic Act, the FDA is required to grant six-month extensions of other marketing exclusivity regimes, including those related to patents or test data protections, as a reward for investments in studies on pediatric patients.[11] Through September 2009, 161 drugs had received pediatric extensions.

In the area of agriculture innovation, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[12] provides for a period of exclusive rights, followed by a period where remuneration based upon cost sharing is required, for purposes of relying upon test data for regulatory approval of certain agricultural chemicals. The U.S. also provides for a certificate of plant variety protection,[13] which

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10 JORDAN GOODMAN & VIVIEN WALSH, THE STORY OF TAXOL: NATURE AND POLITICS IN THE PURSUIT OF AN ANTI-CANCER DRUG (1 ed. 2001).

11 Robert Steinbrook, *Testing Medications in Children*, 347 NEW ENGLAND JOURNAL OF MEDICINE (2002).

12 FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA), 7 U.S.C. § 136 ET SEQ.

13 PLANT VARIETY, 7 U.S.C. (CH. 57) 2321 ET SEQ.

provides 25 years of exclusive rights, subject to several special limitations and exceptions, including compulsory licensing in certain cases.
Each of the *sui generis* mechanisms have features that are different from patents, including for example, different periods of exclusive rights (from six months to 25 years), the possibility to use a resource subject to cost sharing or remuneration, or various requirements or rights of third parties to use of data or information for certain purposes, including for research or government use.

Developers of new medicines, diagnostic devices and other technologies also benefit from extensive federal, state and local government subsidies in terms of grants, low interest rates, or tax concessions. Recently the Office of Budget and Management asked Congress to approve $31 billion in spending at the National Institutes of Health (NIH) for fiscal year 2010, plus other significant spending programs at other federal agencies. NIH spending includes extensive investments in all phases of drug development, including Phase I, II and III stage human use clinical trials.

> B. New proposals are being designed to encourage research in areas where the incentives normally associated with strong patents rights are not considered sufficient, efficient, practical, fair, or relevant.

In addition to the instruments described above, several new approaches are under consideration by policy makers to stimulate, subsidize and reward

investment in medical research and development. These proposals are diverse.

Advanced marketing or purchase commitments have been proposed for a variety of product development needs, including new drugs and vaccines for developing countries[14] or defense against bioterrorism.[15] A novel "priority review voucher" has been implemented for the development of new medicines that treat certain neglected diseases in developing countries,[16]

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14 O. Barder, M. Kremer & R. LeVine, *Making Markets for Vaccines: Ideas to Action*, CENTER FOR GLOBAL DEVELOPMENT (2005); M. Kremer, *Creating markets for new vaccines. Part I: rationale*, INNOVATION POLICY AND THE ECONOMY 35-72 (2000); M. Kremer, *Creating Markets for New Vaccines. Part II: Design Issues*, INNOVATION POLICY AND THE ECONOMY 73-118 (2000); O. Barder & N. Birdsall, *Rescuing the MDGs: Paying for results*, 20 *in* PRESENTATION AT THE FIGHTING WORLD POVERTY CONFERENCE, NEW YORK UNIVERSITY, 15TH SEPTEMBER, AVAILABLE AT HTTP://WWW. CGDEV. ORG/DOC/COMMENTARY/BIRDSALL/MDGSPEECHSEP14. PDF, LAST ACCESSED 06 (2005); M. Kremer & R. Glennerster, *Strong medicine: creating incentives for pharmaceutical research on neglected diseases*, 6 EMBO REPORTS 1-21 (2005).

15 J. Matheny et al., *Incentives For Biodefense Countermeasure Development*, 5 BIOSECURITY AND BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, AND SCIENCE 228-238 (2007).

16 D. B. Ridley, H. G. Grabowski & J. L. Moe, *Developing drugs for developing countries*, 25 HEALTH AFFAIRS 313-324 (2006); AS Kesselheim, *Priority Review Vouchers: An Inefficient and Dangerous Way to Promote Neglected-Disease Drug Development*, 85 CLIN PHARMACOL THER 573-575 (2009).

In 2008, the World Health Organization agreed that:

> Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries.[17]

There is considerable interest in the use of innovation inducement prizes, not only for development of medical products, but innovations in the areas of agriculture, the environment and climate change, and software development.[18]

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17 Global strategy and plan of action on public health, innovation and intellectual property, WHA61.21, Adopted by the World Health Assembly on May 24, 2008.

18 James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHICAGO-KENT LAW REVIEW 1521-54 (2007); James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, Vol. 18 ANNALS OF HEALTH LAW 155-186 (2009); Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 THE AMERICAN ECONOMIC REVIEW 691-707 (1983); Burton Weisbrod, *Solving the Drug Dilemma*, WASHINGTON POST, August 22, 2003, at A21; T. KALIL, HAMILTON PROJECT & BROOKINGS INSTITUTION, PRIZES FOR TECHNOLOGICAL INNOVATION (2006); Bruce G. Charlton, *Mega-Prizes in Medicine: Big Cash Awards May Stimulate Useful and Rapid Therapeutic Innovation*, 68 MEDICAL HYPOTHESES 1-3 (2007); L. BRUNT, J. LERNER & T.

The use of innovation inducement prizes is particularly relevant to the instant case, because many of the proposals for innovation are designed to overcome well known flaws of the patent system, including its inability to reward investments in products that are not protected by patents, or where it is impractical, inefficient or otherwise harmful to enforce the exclusive rights of a patent. It is the nature of scientific progress and innovation that patents can only appropriate some of the value of an innovation, and the restriction of uses of inventions can cause considerable economic waste, pose ethical

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NICHOLAS, INDUCEMENT PRIZES AND INNOVATION. CAMBRIDGE, MA: HARVARD BUSINESS SCHOOL (2008); Selected Innovation Prizes and Reward Programs, 2008 KEI RESEARCH NOTES (2008); K. DAVIDIAN, PRIZES, PRIZE CULTURE, AND NASA'S CENTENNIAL CHALLENGES (2004); Julien Pénin, *Patents versus ex post rewards: A new look*, 34 RESEARCH POLICY 641-656 (2005); J. G. Morgan, *Inducing Innovation Through Prizes*, 3 INNOVATIONS: TECHNOLOGY, GOVERNANCE, GLOBALIZATION 105-117 (2008); Matheny et al., *supra* note___; W. A. Masters, *Prizes for innovation in African agriculture: a framework document*, DEPARTMENT OF AGRICULTURAL ECONOMICS, PURDUE UNIVERSITY AND CENTER ON GLOBALIZATION AND SUSTAINABLE DEVELOPMENT, THE EARTH INSTITUTE AT COLUMBIA UNIVERSITY), 39 PP. AVAILABLE AT WWW. EARTH. COLUMBIA. EDU/CGSD/PRIZES (2004); Joseph E. Stiglitz, *Scrooge and Intellectual Property Rights: A Medical Prize Fund Could Improve the Financing of Drug Innovations*, 333 BRITISH MEDICAL JOURNAL 1279-1280 (2006); Ron Marchant, *Managing Prize Systems: Some Thoughts on the Options*, 2 KNOWLEDGE ECOLOGY STUDIES (2008); James Love, THE ROLE OF PRIZES IN DEVELOPING LOW-COST, POINT-OF-CARE RAPID DIAGNOSTIC TESTS AND BETTER DRUGS FOR TUBERCULOSIS (2008), http://www.keionline.org/misc-docs/Prizes/prize_tb_msf_expert_meeting.pdf.

dilemmas, or discourage collaboration, the sharing of knowledge, materials and technologies, and other elements important for innovation.

In areas where the unhindered freedom to innovate is essential for growth in science, for example, in the interpretation of data or in certain other methods of medical diagnosis, patents are an inferior mechanism to stimulate innovation.[19] It would, in other words, do more harm than good if this Court tailored a test designed, and, importantly, strained, to achieve a particular and Constitutionally unsanctioned social policy relying upon the false assertion that patent mechanisms are the only available instrument to reward successful investments or otherwise stimulate innovation. More importantly, the very existence of these new proposals and mechanisms is evidence that the sky is not in danger of falling on medical research and that those areas which might legitimately lie outside the scope of the patent regime will not go unattended to by other measures. And, indeed, the delicate balance that the patent regime has always employed to determine the exact scope of subject matter will not be maintained if it is upset by speculative dangers that are already being accommodated by both old and new mechanisms alike.

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19 JOHN SULSTON & GEORGINA FERRY, THE COMMON THREAD (2003); Aaron S. Kesselheim & Jerry Avorn, *University-Based Science and Biotechnology Products: Defining the Boundaries of Intellectual Property*, 293 JAMA 850-854 (2005).

C. Global norms for intellectual property provide considerable national discretion in terms of determining the criteria for patentable subject matter, or in providing exceptions to those rights.

With the adoption of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement), WTO members have agreed to abide by certain norms, including under Article 27 of the TRIPS to provide patents in all fields of technology, without discrimination. WTO members retain, however, considerable discretion in implementing these obligations, including importantly in defining the standards for granting patents, the exceptions to patent rights, [20] and to some degree, patentable subject matter, as it relates to the issue of what is an invention, and what is "capable of industrial application." As a practical matter, there is considerable divergence in terms of state practice in several areas, including patent policy in the areas of medical and agriculture technologies, software, patenting of genes, and other topics, [21] and the Court has the freedom to chart its own course in the instant case, particularly as regards to patentable subject matter.

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20 Articles 27.2 and 27.3, and Articles 30, 31 and 44.2. of the TRIPS Agreement.

21 UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT (2005).

CONCLUSION

The patent system plays an important role in the economy[22], but patents are not the only instrument available to policy makers to stimulate or reward investments in the development of new products and services. In areas where patents are not available, relevant, or where they impose excessive costs on society, policy makers have ample options to fashion non-patent incentive mechanisms or subsidies. Patents should only granted and their rights extended and enforced in areas where the benefits of doing so exceed the social costs, and where no superior alternative mechanisms exist -- as the balance struck by the Constitutional Clause was intended to accomplish.

The area of medical innovation is one of the most vexing areas of innovation policy. On the one hand, persuasive claims are made regarding the need to stimulate investments in new discoveries and technologies, including those relating to the interpretation of data. However, any measures that create legal barriers to the diagnosis or treatment of an illness, or to research to find new tools to combat illnesses, present enormous risks and costs to society. To the extent that patents are not available or enforced in a particularly area of medical care, policy makers have demonstrated keen insights into the many different ways that incentives can be fashioned, including methods that are less harmful

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[22] Michael H. Davis, *Patent Politics*, 56 S.C. L. Rev. 337 (2004)

to science and patient interests than legal monopolies on processes or uses of data.

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