

ACO pilots. Because transforming primary care in accordance with the medical home model requires considerable resources, incentives for both quality and savings should emphasize high levels of primary care performance to ensure that ACOs provide adequate support to their primary care providers to enable them to attain and sustain the essential capabilities of a PCMH.

These two approaches are synergistic models of delivery-system reform that, together, promise to redirect the U.S. delivery system toward reduced cost growth and improved quality. ACOs will require a strong primary care core to succeed and, in turn, can provide essential delivery-system infrastructure beyond the primary care practice to ensure the full realization of the PCMH model. Ongoing evaluation of both models, preferably in combination and in diverse settings, is essential. Demonstrations should be de-

signed as pilot tests that can be continued if successful, modified as necessary, and (when successful) implemented broadly, with continued adaptation. Finally, one of the most important elements of federal health care reform will be expanding the capacity of federal agencies, including the Centers for Medicare and Medicaid Services and the Agency for Healthcare Research and Quality, to implement, support, and evaluate these promising delivery-system reforms.

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Robert Berenson, M.D., Karen Davis, Ph.D., Kevin Grumbach, M.D., David Meyers, M.D., Hoangmai Pham, M.D., M.P.H., Robert L. Phillips, Jr., M.D., M.S.P.H., and Dana Gelb Safran, Sc.D. The consensus that emerged from the discussion and that is summarized in this article should not be taken to be the perspective of any specific individual or organization.

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The Supreme Court, Process Patents, and Medical Innovation

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On November 9, the U.S. Supreme Court heard oral arguments in *Bilski v. Kappos*, one of the most closely watched cases in the Court's current term. The central question involves the legitimacy of a patent on a method for hedging risk in commodities trading, but the outcome will have important implications for health care delivery and research. Although patents covering medicines, devices, and research targets such as DNA sequences have become commonplace, in recent years there has been a surge in new patents on medical processes.¹ Patents have

been awarded for processes such as making diagnoses, performing surgery, making prescribing decisions, and other methods for treating patients and engaging in research. The *Bilski* case represents the first time in nearly three decades that the Supreme Court has considered the standard for issuing process patents.

Patents — government-sponsored monopolies allowing inventors to exclude others from using their intellectual property for 20 years — are granted under the constitutional authority to “promote the progress of Science and the Useful Arts” and are con-

sidered necessary by some observers to encourage investment in innovation. The Patent Act establishes that patentable inventions must fall within one of four categories: process, machine, manufacture, or composition of matter.

Efforts to define a patent-eligible “process” have been fraught with controversy. The Supreme Court has long rejected attempts to patent scientific observations, mathematical formulas, or abstract principles — such as Samuel Morse's effort to patent the concept of using electromagnetism to communicate language (see table). Yet patents have been

Important Past Supreme Court Cases Affecting the Scope of Patent-Eligible Processes.			
Case	Date	Invention at Issue	Holding Summary
<i>O'Reilly v. Morse</i>	1853	The use of electromagnetism for printing letters or characters at any distance	Not patentable: patent claims cannot cover all conceivable uses of a particular natural principle.
<i>Cochrane v. Deneer</i>	1876	A method of manufacturing "superfine" flour	Patentable: patent describes a process used to treat the materials and transform the flour into a different state.
<i>Gottschalk v. Benson</i>	1972	A process for converting binary-coded decimal numbers into pure binary form	Not patentable: patent describes an overly broad claim to a basic mathematical formula.
<i>Parker v. Flook</i>	1978	A process for identifying abnormal conditions in the catalytic chemical conversion of hydrocarbons	Not patentable: general scientific algorithms are not patentable, and tying an algorithm to one particular use does not change that.
<i>Diamond v. Diehr</i>	1981	A method of curing synthetic rubber that uses the Arrhenius equation to calculate the optimal cure time	Patentable: the formula is a part of an inventive process for curing rubber.

approved for innovative processes that use laws of nature; for example, a system for curing rubber that uses the Arrhenius equation to determine when curing is complete is a patentable application of a natural law of chemistry. Navigating this distinction became challenging for the Patent and Trademark Office, so in the 1990s, the Court of Appeals for the Federal Circuit established a test for judging processes: a patentable process should produce a "useful, concrete and tangible result."

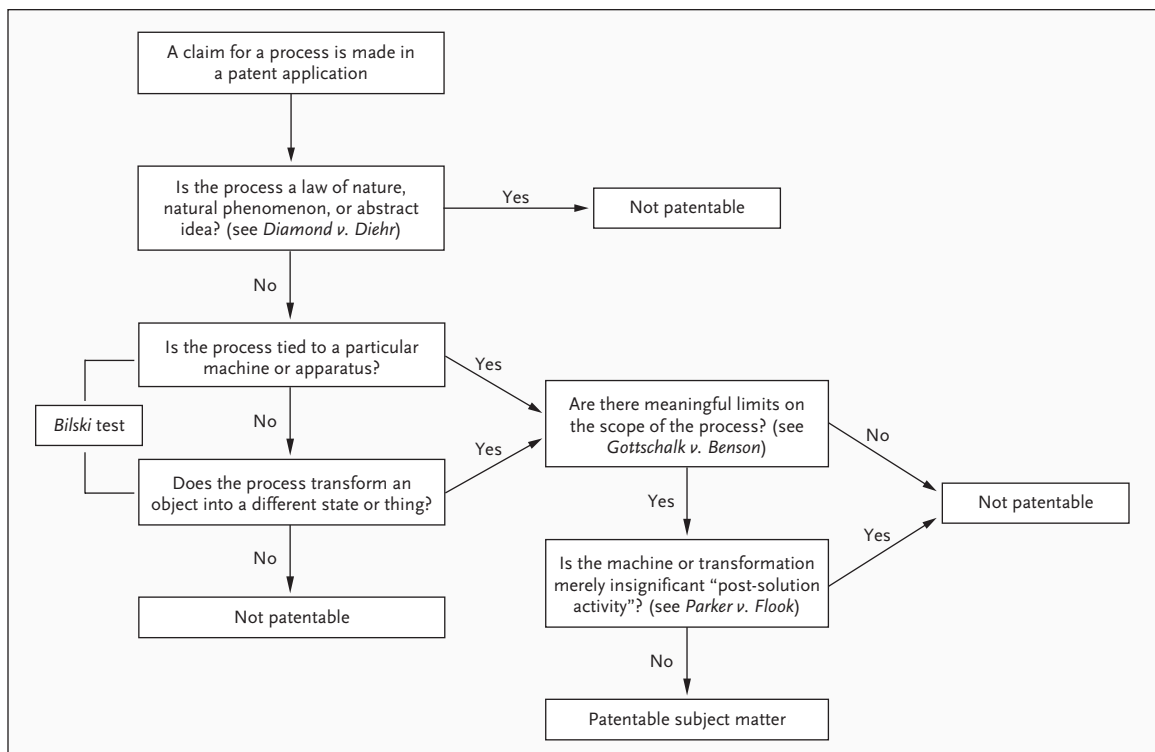
That test, however, proved ineffective at weeding out inappropriate process patents. In one case, the Patent Office approved a patent for a diagnostic method that used elevated blood homocysteine levels to determine that a patient had a cobalamin (vitamin B₁₂) or folate deficiency. The laboratory-services company that owned that patent sued a competitor to prevent it from using a different homocysteine assay that would lead to the same diagnostic conclusion. That process claim was upheld in court, despite the fact that the process

amounted to little more than a mental correlation made by the physician receiving the homocysteine test result. The patent remained in effect when the Supreme Court chose not to review the case, *LabCorp v. Metabolite*, although Justice Stephen Breyer, joined by Justices John Paul Stevens and David Souter, issued a dissent criticizing the "useful, concrete and tangible result" test, arguing that it was not based in precedent and had no clear limits.²

Numerous other questionable process patents have been awarded in recent years, particularly in medical research and health care delivery. Such patents are problematic when they seek to monopolize basic scientific phenomena. For example, Ariad Pharmaceuticals obtained a patent on a method of inhibiting gene expression by "reducing NF- κ B activity in the cell." Ariad then sued Eli Lilly for infringement because two of Eli Lilly's drugs, drotrecogin alfa (Xigris) and raloxifene (Evista), modulated this enzyme. Ariad won a \$65-million judgment in District Court before the deci-

sion was reversed by the Federal Circuit; it remains under appeal.

Other patents claim a monopoly on natural thought processes that physicians use in patient care. For example, a medical informatics company obtained a patent on a process for selecting a treatment regimen on the basis of characteristics of the patient, the disease, and the therapeutic options. The company then claimed infringement by Stanford University's HIV Drug Resistance Database, an open-source computer program that allows physicians to enter patients' viral genetic information and retrieve results regarding drug resistance, which can be used in devising treatment regimens.³ There are patents on methods of treating diseases (e.g., treating rheumatoid arthritis with combination drug therapy) and on methods of identifying adverse events in a drug-safety database. These processes all produce "useful, concrete and tangible" results, but they also seem to cover fundamental principles of disease management (a physician's decision to pick a drug on the basis of disease



Using the *Bilski* Machine-or-Transformation Test to Assess Whether a Process Is Patentable.

This test was announced by the Federal Circuit and is currently under review by the Supreme Court. With regard to the transformation portion of the text, the Federal Circuit comments specifically that “in most cases, gathering data would not constitute a transformation of any article.”

characteristics) or public health (observing a relationship between drug use and adverse events).

In *Bilski*, the Supreme Court has the opportunity to clarify the way process patents should be evaluated. The issue in the case is a patent application regarding a method for commodity trading. The inventors, Bernard Bilski and Rand Warsaw, described a hedging strategy that can reduce risk in business situations in which prices often fluctuate. The process involves having an intermediary buy commodities at a fixed price from a producer and then sell them at a fixed price to a consumer. The Patent Office initially rejected this patent on the grounds that it “merely manipulates [an] abstract idea and solves a purely mathematical

problem.” On appeal, the Federal Circuit, perhaps inspired by the *LabCorp* case, agreed that the process was unpatentable and set out a new “machine-or-transformation” test for evaluating process patents: if the process is not tied to a particular machine or apparatus, or does not transform an object into a different state or thing, it is not patentable (see flow chart). The inventors appealed this rejection to the Supreme Court. At oral arguments, the Justices acknowledged concerns about the wide scope of process patents, while also questioning whether the machine-or-transformation test was too rigid to permit appropriate patents on future technologies.

The *Bilski* case may ultimately help to rein in the proliferation

of questionable patents. For example, the machine-or-transformation test was recently used to invalidate both a patent on a method of increasing the bioavailability of the muscle relaxant metaxalone by administering the drug with food⁴ and a patent on a method of identifying a link between immunizations and side effects that involved immunizing a treatment group and comparing it with a control group in terms of the incidence of chronic immune-mediated disorders.⁵

Innovative clinicians and researchers should be able to patent specific processes containing well-circumscribed physical steps. However, the law should not allow patents on concepts, correlations, or natural pathways that people happen to discover, such

as a link between vaccination schedules and immune-mediated disorders. Such processes are not appropriate for patents in part because, at least in health care, patenting them frustrates the objectives of scientific discovery in at least three ways. First, physicians' decision making may infringe on such a patent, and liability can also arise from efforts by universities or educational companies to disseminate knowledge about new diagnosis or treatment strategies. Second, the need for licenses and royalty payments increases the cost of health care delivery and research and can decrease access to essential medical services. Third, the patents

can impede subsequent medical innovation that builds on the basic scientific principle at issue. For example, Myriad Genetics owns patents on the use of the *BRCA1* gene for assessing the risk of breast cancer, which can prevent the development and use of improved genetic tests that better identify at-risk patients.

The recent expansion in the scope of process patents is at odds with the patent system's constitutional goals. If the Supreme Court upholds the machine-or-transformation test in *Bilski*, it could help prevent abuses in this area of the law, with potentially large benefits for several sectors, including health care.

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The Breadth of Hopes

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Hoping is a fundamental human activity. As a pediatrician who cares for children with life-threatening, complex chronic conditions, I hear the word "hope" on a daily basis: "I hope we can come up with the definitive diagnosis"; "I hope the treatment makes the disease go away"; "I hope we can relieve his pain"; "I hope we can go home today." Indeed, the word is uttered so frequently in clinical medicine that the underlying phenomenon is widely presumed to be well understood, a shared point of reference. Our understanding of hope, however, is not based on much empirical evidence about how hope actually does whatever it does in shaping our lives. Moreover, as with many everyday phenomena, when our conceptions of and assumptions about hope are examined carefully, they prove to be extremely varied. In this case, they are also limited, radically affecting —

and too often curtailing — our approach to hope as a force in our lives.^{1,2}

To make the most of hope's benefits, it would help to replace four prevalent presumptions about hope with alternative propositions. First, we often speak of hope as a single entity — big, blooming, and beckoning — with no internal architecture. Within this conceptual framework, which is related to the notion of "feeling hopeful," hope is alluring but vague, revered but ineffable, aloof from daily life and mostly inactionable. In contrast, we also frequently mention specific hopes, of "hoping for" something in particular. Unlike the broader concepts of hope and feeling hopeful, these discrete acts of hoping — smaller, salient, and steady — provide motivation and direction toward a desired goal.

What happens if we shift away from the monolithic vision

of hope and toward the proposition that hope in the big sense is actually composed of multiple hopes in the smaller sense?³ This perspective casts several common concerns about hope in a new light and suggests some important corollaries for clinical practice.

Second, when clinicians discuss the prospect of delivering bad news to patients or their families, we often speak imperatively about not "taking away" or "killing" or "destroying" their hope. Yet if hope writ large is in fact a collection of smaller hopes, to which of the various possible hopes does the imperative refer? Usually, the focus of paternalistic concern is on the distinct hopes of cure or long-term survival, which are exactly the types of hope that are most threatened by bad news. Indeed, such news often elicits feelings of intense sadness or anger in patients and families. But as countless patients and par-