Two developments this month have underscored the breadth of dissatisfaction with the current state of biotechnology patenting, even as the court weighs a summary judgment motion in the pending ACLU-sponsored litigation against Myriad Genetics' breast cancer gene patents. First, on October 2, 2009, the American Medical Association and four other medical organizations interested in genetic medicine filed an amicus brief in Bilski v. Kappos, which is now before the Supreme Court. In a decision in Bilski late last year, the Federal Circuit rejected a patent on a method of hedging in a commodities market because it was a nontransformative process consisting solely of mental steps. The Federal Circuit promulgated what has come to be known as the machine-or-transformation test, which limits patentable subject matter to processes that are either tied to a particular machine or transform the state of matter. The test has been attacked by various biotechnology and pharmaceutical interests because of its perceived limiting effect on patenting diagnostic techniques and tests.

The AMA’s brief (pdf), not surprisingly, supports the Federal Circuit’s Bilski decision, although it argues that it does not go far enough. Bilski’s claims are not patentable, the brief argues, not so much because they fail to use a machine or make a physical transformation, but “because their lack of machine or transformation indicates that they do not involve what has traditionally been considered to be patentable subject matter”—that is, because they preempt basic scientific principles. Applying this logic to medical diagnosis, the brief argues for a narrowing of what is patentable: “the preemption standard prevents patentees from attempting to cover every possible application of a scientific observation, and requires them to limit their claims to a particular new and useful application or use of the observation.” On a policy level, the brief contends that scientific relationships with diagnostic significance represent the kind of knowledge that physicians are ethically obligated to share, and that allowing patent monopolies on such knowledge will detract from the quality of health care and add to its cost.

The AMA brief also attacks the Federal Circuit’s September 16, 2009 decision in Prometheus Laboratories Inc. v. Mayo Collaborative Services, in which it held that methods for calculating optimal drug dosages for treating autoimmune diseases satisfied the machine-or-transformation test. According to the AMA’s brief, that patent extends to “the basic fact that certain test results correlate with a given physical condition,” and “would preempt the physician from doing anything with the knowledge” when “it should be used in the diagnosis and treatment of patients.” While the AMA’s brief does not directly attack gene patents such as Myriad’s, it does bear on other claims at issue in the ACLU litigation that are directed methods of testing and interpretation.

Then, at a public meeting earlier this month in Washington, the Task Force on Gene Patents and Licensing of the Health and Human Services (HHS) Secretary’s Advisory Group on Genetics, Health and Society (SACGHS) presented a report recommending potentially far-reaching statutory and policy changes in the biotechnology patent regime. (Webcasts and other materials from the meeting are available here, and summaries of the meeting are available from GenomeWeb and the PHG Foundation.) Most significant is the recommendation of an exemption from liability for infringing gene patents for making, using, ordering, or selling a patient care test. Note that this would not invalidate gene patents, but simply make them unenforceable against those engaged in testing for patient care—on the model of the current law that makes surgical technique patents unenforceable against surgeons. A second recommendation is an exemption for those using patented genes for research purposes. The Task Force also urged that HHS discourage (in unspecified ways) what it called “simple association patent claims”—presumably a reference to Prometheus-type claims—because of their potential to preempt basic laws of nature. SACGHS’s final report is expected in December.

The Task Force was motivated by its belief that while gene patents do not serve as “powerful” incentives for investment in genetic research and genetic testing, they may limit clinical access to tests. Much of the commentary at and surrounding the Washington meeting was directed at Myriad and its BRCA1-2 patents. A patient advocacy group called Facing Our Risk of Cancer Empowered urged SACGHS to monitor and regulate the direct marketing of genetic testing to consumers and doctors by Myriad and others. Mega-health insurer United Healthcare charged that as many as 80% of the women getting Myriad’s BRACAnalysis test don’t need it, and announced a prior notification requirement for Myriad tests. The Task Force itself referred to the problem of patent-based “sole providers” limiting access to tests and stifling competition, and stressed that unpatented genetic discoveries “routinely” lead to clinical tests. Its belief is apparently that breaking patent monopolies will lead to more competitive markets without taking away the incentives needed to make the fundamental discoveries that underlie genetic testing. Although others, including members of the Task Force and the Biotechnology Industry Organization (BIO), have voiced their displeasure, Myriad has not yet commented publicly on the recommendations, but it would presumably disagree as well, raising the don’t-kill-the-geese-that-lays-the-golden-eggs argument.

These recommendations have a long way to go before becoming law. The biggest hurdle, of course, will be Congress, which has thus far been unresponsive to the hue and cry to rein in biotechnology patents in any significant way. The recommendations themselves leave some major questions unanswered, including how testing for patient care purposes will be defined, and what kinds of “research” would fit under the proposed exemption. What about, for example, the R&D efforts of for-profit direct-to-consumer (DTC) genetic testing companies?

Even less clear (to me, anyway) is who is right in this debate. In the draft report it issued last spring, SACGHS acknowledged that the evidence on gene patents impeding research was equivocal. A recent study in the journal Nature Biotechnology on “Legal uncertainty in the area of genetic diagnostic testing” does little to suggest that the situation has cleared much in the past year. While the ACLU and others have marshaled some compelling horror stories about patents contributing to limited clinical care options, I tend to be dubious about building policy on the alleged malfeasance of a single company. And when a company like United Healthcare enters the debate as a friend of consumers, I become even more suspicious. I also wonder if the assumption that genetic testing would continue to develop without enforceable patents might not be a bit glib—hope masquerading as evidence?

One thing that is clear is that Myriad’s patents (and others like them) are now under siege from every conceivable direction. (Although Myriad is not showing any signs of slowing up in its attempts to develop diagnostic genetic tests based on issued gene patents, as evidenced by last week’s announcement that it had entered into an exclusive license with Johns Hopkins University for the rights to JHUs patents related to the
PALB2 gene, which is indicated for an increased risk of pancreatic cancer.) If the ACLU’s primary motive was to raise public awareness of gene patents and what they do, it has succeeded spectacularly. All this should have little if any influence on the outcome of its case at the district court level—the law seems clear that genes are patentable. However, the Federal Circuit and the Supreme Court, if it ultimately takes the case, will have considerable freedom to rethink what the Patent Act—drafted before Crick and Watson—“says” about gene patenting, and these sorts of policy arguments could well tip the balance.