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AEI Panelists Debate Patent Reforms, Need for Greater Certainty

By Susan Carhart

The American Enterprise Institute Legal Center for the Public Interest held a forum in Washington Sept. 25 to debate the Patent Reform Act of 2007, now pending in Congress, and to introduce a book by AEI's Claude Barfield and John E. Calfee on biotechnology and the patent system.

The clear message coming from a Sept. 25 forum at the American Enterprise Institute is that both the American economy and national competitiveness in biotechnology, computer software, and other high-tech sectors require more certainty in the patent system. Raising the level of confidence in assessments of the validity and value of U.S. patents was the touchstone by which panel members of every stripe and constituency appeared to judge changes being proposed in the Patent Reform Act of 2007 (H. 1908, S. 1145).

Patents, Biomedical Research

Ashish Arora of the Heinz School at Carnegie Mellon University presented research on the importance of patents. Patents are valuable even in industries that do not patent a lot because they stimulate research and development, he said. They are used for licensing by small companies and commercialization by large ones.

Arora also discussed some negative aspects of patenting. Excessively broad patents are a problem, especially when owned by inexperienced players such as universities or those with no long-term interest in an industry, Arora said. He said universities also are inexperienced in the licensing business.

Patents have the potential to be roadblocks to innovation, he said. "This hasn't happened yet, but the preconditions exist" in the biopharmaceutical industry, where there are diffuse ownership of patents, inexperienced owners, and owners with limited stakes in production. Researchers seeking commercial applications are a principal cause of research being diverted or delayed, he said.

Foundational or research tool patents particularly may block follow-on research, and it is unclear what the law can do about this, Arora said. Society should be careful in seeking to correct this problem, he said, because "creating more red tape and bureaucracy will reduce scientifically valuable but commercially low-value research."

Patents covering diagnostic tests are the most contentious and create the largest public policy dilemma, Arora said. He cited "a firm that owns a patent, tightly controls its use for testing, and sent a cease and desist order to a university laboratory."

Another problem occurs when only one test center is using a test. "It means a patient cannot get a second opinion," Arora said.

He described what often happens when researchers confront university patent roadblocks. After seeking permission, getting pushed "back and forth," and ultimately being denied, "most of the time, they just infringe," he said. One audience member called this a "self-correcting mechanism" for the roadblock problem.

"It is not in anyone's interest to sue. For what? What would be the damages?" Arora said.

To help alleviate problems in the patent area, he said the mission of the Patent and Trademark Office should be changed to serve not inventors, but society. "This is a big part of the problem," he said.

Arora added that he objects also to legal discrimination against business models based on licensing, for example, where courts rule that if an infringer is producing something with a patent, the patent holder is entitled to an injunction, "but if not, no injunction."

In knowledge-based economies, "prejudices in favor of material production are simply that," he said. Arora said engineers and not lawyers should write patents. When lawyers write them, they cannot tell what they are for, he said.

Taking Long View

Richard Johnson with Arnold & Porter in Washington said he found the book introduced at the forum—*Biotechnology and the Patent System: The Economic Implications of the Proposed Patent Reform Act of 2007*—by AEI's Claude Barfield and John E. Calfee, was "balanced and insightful" and "a useful political road map" that reminds that change sometimes leads to unintended consequences.

He delineated, however, five issues that he said the book did not develop—university research, self-correcting remedies to systemic problems like the hindrance of innovation, how policy perspectives change when intellectual property (IP) issues are examined more broadly with IP property rights as a subset, convergence issues such as bionanotechnology and bionanotech IT, and the failure to consider patents in the international context.

Johnson said foreign companies are experimenting with many different research and business models, citing efforts by the Organisation for Economic Co-operation and Development since 2002, German Chancellor Angela Merkel's push for a "knowledge creates markets" approach, and the "huge" number of patent pools and connectivity ventures seen in Japan.

"We have to keep abreast of what is happening internationally," he said, adding that he is fearful that the United States is lagging in biotechnology.

Referencing the Bayh-Dole Act, which allows small businesses and universities to retain title to inventions made under federally funded research programs, Johnson asked how such provisions should apply in terms of multidisciplinary and global research.

"Some universities are concerned that their technology transfer offices are second only to the football team" in lack of integration with the broader university purpose, he said.

Too many investors want nothing to do with universities, which they equate with "monopoly and bottleneck."

"We need new models to keep the benefits of the Bayh-Dole Act and technology transfer, ones that are more effective in getting discoveries to the public.

"The linear tech transfer model is outdated."

Johnson suggested exploring free agency status for academics, creating competition in third parties, regional alliances, and teaming models.

The forum discussion then shifted to the Patent Reform Act pending in Congress (1 LSLR 473, 9/14/07).

Patent Reforms Debated

Bryan Lord, a member of the Innovation Alliance and general counsel and vice president of finance and licensing at AmberWave Systems in Salem, N.H., sought to dispel five patent "myths," including that litigation is out of control. Given the growth in the high-tech sector, the number of lawsuits filed has been consistent over the last 15 years, he said. And, contrary to reports of a supposedly stratospheric

damages trend line, awards dropped to \$3.1 billion in 2006 from 2005's \$5 billion, he told BNA Sept. 27. Andy Cadel, managing director and chief intellectual property counsel at JPMorgan in New York, described the problems uncertainty in the patent system creates for investors.

It is hard for investors to get any objective analysis on "how dangerous" existing patents are when evaluating a potential investment in new technology. "The tendency then is to overvalue them," he said. Robert Armitage, senior vice president and general counsel at Eli Lilly and Co., addressed another source of uncertainty and how it creates inefficiencies in the patent application process. He spoke of how fear of being accused of inequitable conduct leads attorneys to want to "tell [the patent examiner] everything and say nothing."

Anthony Figg with Rothwell, Figg, Ernst & Manbeck and the American Bar Association task force on patent reform said this fear causes attorneys to submit millions of pages of paper to the patent examiner—everything from every arguably relevant prior art reference to the entire pleadings in possibly relevant patent litigation—in order to avoid being accused of withholding information from or misleading the examiner.

Armitage praised a provision in the Senate patent reform bill that would help reduce this costly and wasteful practice by adopting a materiality standard for accusations of attorney misconduct. Figg agreed inequitable conduct law is "much overused." Not only is it a drag on the system, but it makes litigation extremely complex, he said.

Figg said he believes reforms also should focus on reducing other subjective elements in the patent system. For example, the ability to obtain enhanced damages for willful infringement of a patent should be limited to cases in which a party can meet a heightened standard for showing improper conduct. Like most panelists, Figg was in favor of post-grant review. Establishing a post-grant window—a limited period during which patent oppositions may be filed—would help ensure good patent quality by allowing all issues of patent validity to be raised.

Reforms Would Reduce Uncertainty

Cadel said he believes patent reforms now pending on Capitol Hill would reduce uncertainty and doubt. Post-grant review would help investors more accurately value patents, as would the provision of interlocutory appeal for claims construction rulings. That there is no current option to appeal a ruling before the end of a lawsuit is "very challenging for our economic marketing," he said, leading to a tendency to overvalue outside patents.

On another subject, Cadel also had praise for provisions in the House bill that would make tax methods unpatentable. "The ability to patent a tax method lets someone put a toll on legislative intent," blocking use of a tax law provision and making it hard to use, he said.

Mark Chandler, Cisco general counsel and member of the Coalition for Patent Reform, called the current reform push "a great litigation reform opportunity."

As in the larger legal system, there is a great deal of abusive patent litigation and many more multi-defendant cases than in the past, he said. It's a "giant and arbitrary tax on the patent system."

Chandler estimated that companies can count on spending \$3 million if an infringement case is decided on motions and \$10 million if it goes to trial. They also have to deal with people who try to game the system by forum-shopping.

Moderator Ted Frank, director of the new AEI Legal Center for the Public Interest, which hosted the event, agreed, saying the law should be changed so that patent cases "won't always be tried in Marshall, Texas."

Venue reform "can't be mentioned enough," Cadel agreed. In pro-plaintiff, pro-patent holder courts like the Eastern District of Texas, it is not possible to know "what a jury will latch onto," making it very hard to

value a patent because "you can't settle a case."

NIH/Patent Interaction

Mark Rohrbaugh, director of the Office of Technology Transfer at the National Institutes of Health, discussed that agency's patent philosophy. "Patents are not good or bad; it's how you use them," he said. Despite studies showing that patents do not discourage research, NIH recognizes that they can create roadblocks and administrative delay. It therefore encourages researchers not to patent a discovery unless it is necessary to facilitate further research. "Inventions can be licensed without being patented," he said.

His office even considered not using material transfer agreements, but NIH lawyers objected, "So we've slimmed them down," Rohrbaugh said.

As for exclusivity at NIH, "even here we encourage it to be tailored to a particular use," Chandler said. "We prefer narrow exclusivity agreements."

NIH researchers also "freely share" pre-competitive space, he said, citing as an example the work of the Biomarker Consortium, a public-private biomedical partnership founded in 2006 to find and validate new bio- markers and tools.

An audience member asked why NIH makes so little use of its "march-in authority" under the Bayh-Dole Act's mandatory licensing provision designed to prevent the underutilization of federally funded inventions. Chandler responded that the authority is a "sledgehammer" suitable only for the most extreme cases and of little use when a more delicate instrument is needed, such as when NIH objects to a fee being charged or when a pricing issue comes up.

Furthermore, he said, exercising march-in authority requires granting a "fair amount of due process and we're an agency that has not got any kind of administrative or judicial process at all.

"Regulations are not written and would take a long time. Also, the decision would be held in abeyance until all administrative appeals are exhausted.

"March-in authority is more of a threat than a real tool," Chandler said.

Damages Apportionment

Damages apportionment is another area in critical need of reform, the panelists said. Most acknowledged problems with the current system of having jurors apply the 15-part *Georgia-Pacific* test, especially factor 13, which requires an accused infringer to show damages should be apportioned rather than based on the entire retail or other value of the total product.

Depending on the product, failure to apportion damages can lead to massive damages verdicts, Armitage said. He gave the example of Alcatel's case against Microsoft for allegedly infringing patent technologies related to MP3 compression, where—having calculated damages on the retail value of the total computer, not just the infringed patent's contribution to the value of the product—a jury decided damages should be \$1.5 billion. A court later reversed the finding of infringement altogether.

Throughout the discussion, Armitage often was the odd man out, stating that, for example, so-called patent "reforms" over the years have left the 18th century system largely intact.

U.S. patent law was "originally written in 1790 and is largely untouched," he said. Changes made in 1952 were not a major revision, he said. "1836 was the last real revision" and left the law "with the same original principles."

In the ensuing years, Armitage said, "with no interest in patents by Congress," the courts have been "truly magnificent" in making the law work. As a result of court decisions, "juries no longer decide what patents mean, courts do it as a matter of law." Over the years, courts also limited the "doctrine of equivalence" so that it now applies only to insubstantial changes. They also now grant punitive damages only in cases of

truly reckless infringement.

Thus, while the patent system has problems, statutory reform is not necessarily needed to solve them all, Armitage said. For example, the "lawsuit abuse agenda" should not be a major reason for patent reform, he said; the tort system has more significant abuse issues. "Patent damages are fairly modest compared to tort system awards," he said.

Still, if the law is not made to work well in a 21st century world, Armitage said, "I truly worry that the patent system will break down."

Information on the policies and procedures of the Biomarker Consortium is available at <http://www.thebiomarkersconsortium.org/>

A comparison of the House and Senate patent bills is available on the Web site of the Intellectual Property Owners Association at <http://subscript.bna.com/UTILS/lk.nsf/r/scat77enve?opendocument> (click on "Patent Reform" and see "Resources").

"Agenda for 21st Century Patent Reform," a white paper of the American Bar Association section on intellectual property, is available at <http://www.abanet.org/intelprop/home/PatentReformWP.pdf> . The AEI Web site is <http://www.aei.org> .

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