ing, modeled on software, might be applied to genomics research as an alternative to the patenting tradition. Jerome Reichman, Bunyan S. Womble Professor of Law, and Tracy Lewis, Martin Black Professor of Economics and director of the Innovation Center at the Fuqua School of Business, who has a cross-appointment at Duke Law School, will explore how a regime of compulsory liability rules could work as an alternative to property rights in the context of genomic science and industry. (See related stories, pages 30 and 33.) The Center also includes faculty from Duke's Sanford Institute of Public Policy, School of Medicine, and Department of English, as well as Georgetown University's Kennedy Institute of Ethics, with its DNA Patent Database.

"To do good work in this area, you need business, law, science, and ethics," Cook-Deegan says. "Duke has pulled this all together; it's extraordinary."

By design, the new Center will look at alternatives to the traditional intellectual property framework.

"If there's anything that resonates as belonging to all of us, it's our genes," observes Cook-Deegan, noting that some pioneering genomics researchers argue for the practical value of a robust scientific commons, an area of focus by Duke Law scholars such as Rai, Reichman, and William Neal Reynolds Professor of Law James Boyle.

"At the same time, you have another set of players operating in the private sector, doing the same experiments, generating the same data, but handling it in a completely different way. There's a chance here to compare how those different frameworks play out," Cook-Deegan explains.

The genetic field is unusual in part because of a limited number of genes—about 22,000 in the human genome—that produce approximately 100,000 proteins. Argues Cook-Deegan, "If you allow exclusiv-
ity over genes, then you are really building fences around things that everybody needs access to in order to make scientific progress. When you have a system bounded by nature, there is the potential for bottlenecks. Bottlenecks and exclusive property rights are a volatile mix.”

While early genetic innovations of the mid-1970s were not patented, the norms shifted rapidly toward patenting in academia, partly as a result of the Bayh-Dole statute of 1980 that gave universities the rights to the intellectual property they create with federally supported research, according to Cook-Deegan. “When biotechnology and pharmaceutical firms started pouring research and development money into molecular biology in the 1980s, their business models depended on patents. Everybody was patenting, but for somewhat different reasons.

“The default premise has shifted over 30 years from a certain skepticism regarding the value of patents to ‘we love patents.’ And patents have been applied to more and more things, including fairly basic methods—genes in their purified forms, cells, cell-lines, software, even methods used in computer—all sorts of things people produce in molecular biology laboratories.

“Only through litigation can the validity of these patents be tested,” Cook-Deegan adds. Since litigation usually only becomes worthwhile once products get to market—generally a 15- to 20-year cycle in pharmaceuticals—that process is just getting underway. “The surge in DNA patenting really began in 1994,” says Cook-Deegan, citing data from Georgetown’s DNA Patent Database (http://dnapatents.georgetown.edu), a unique data resource for the new Center. “And the peak may have passed, based on drops in DNA patent counts each year since 1999.”

The cumulative nature of innovation in genomics makes intellectual property a critical concern. “Some companies love patents, but at the same time hate gene patents,” explains Cook-Deegan, offering as an example companies that make DNA “chips,” which necessitate the use of hundreds of thousands of gene segments. “They want to patent their technologies, but don’t want to have to pay royalties on every single DNA segment they use.”

Other companies base their entire business plans on strong patents on genes—they find genes and patent them so that they get licensing fees. “These companies have a huge stake in opposing patent reform that might limit their intellectual property,” argues Cook-Deegan. “Somebody has to be looking out for the public interest, and this is part of the Center’s role.”

Cook-Deegan cites examples where private and public interests have found an acceptable balance. Gene splicing, or recombinant DNA, was one of the two seminal genome technologies of the 1970s. The “Cohen/Boyer” patent was held jointly by Stanford University and the University of California (Berkeley) until its expiration in 1997, covering both a powerful research tool and production mechanism. Instead of exclusively licensing the technology to a single company, the universities licensed it relatively cheaply for commercial users to ensure that it generated revenue, and built a de facto research exemption—academics could use it for free.

“The patent generated a quarter-billion dollars that the universities plowed back into research, but the patent did not block extremely wide adoption of the method, and it had little if any effect on prices of the drugs made using recombinant DNA.

“The crucial issue is not just what is patentable or not, but how the patents are used and licensed. Patents don’t inherently help or hinder innovation,” explains Cook-Deegan. “Patents can do both, and sometimes a single patent can do both at the same time, but in different ways for different applications.

“A consensus is emerging that patents are not working well in DNA diagnostics,” he continues. “Groups that were doing some DNA tests have stopped because of the intellectual property; prices are higher, and incentives to innovate are lower. The patents basically cover an association between DNA sequence and disease—a basic discovery—but the genetic test that follows may not require extensive investment to develop. Any lab can do the DNA test just knowing the association. The patent holder has little stake in doing the test cheaper, faster, or more accurately because price and profit are driven by the monopoly, not technology. Why spend money to slim down a cash cow?

“We’re hoping to add to the debate a mix of people who are thinking of it from the perspective of the system as a whole and the public interest, not just vested interests,” says Cook-Deegan. “The vested interests may reach decisions that are fine for all of us most of the time, but when they aren’t, we’ll be watching.”