US Supreme Court rules patents on 'natural' human genes invalid

In one of the most anxiously awaited court decisions of the year, the US Supreme Court today unanimously struck down patents on isolated, natural human genes.

Patents on synthesized DNA, however, are still valid, the justices said. Included in that category are commercially important patents on cDNA — segments of DNA synthesized using an RNA template.



The case pitted the American Civil Liberties Union (along with a host of patients, advocates, researchers and professional societies) against Myriad Genetics, a genetic testing company based in Salt Lake City, Utah, that held patents on two genes associated with breast and ovarian cancers. During its four-year run, the lawsuit has drawn attention to the debate over gene patenting, but many have argued that the outcome of the case would have little practical bearing on biotechnology or genetic testing because the patents in question are relatively rare. Myriad's test, for example, is protected by other patents that are not limited to isolated DNA sequence.

Regardless, both sides claimed victory today. The American Civil Liberties Union said the ruling would benefit patients by opening up the genetic testing market to competitors. Myriad, meanwhile, stressed the validity of its cDNA patents and noted that Supreme Court justices were careful to highlight the continued validity of patents on methods of analysing DNA. The company's stock spiked after the ruling came down today.

But Mark Lemley, a professor of law at Stanford University in California, says that biotech patent owners shouldn't necessarily break out the champagne. Any patent like Myriad's can now be avoided by basing genetic tests on genomic DNA rather than cDNA, he says, a practice that is more common now as new DNA sequencing methods infiltrate the clinic. And cDNA patents may not be safe from other kinds of challenges, he adds, because the process of making a cDNA is widely known and practised. "Even though cDNA is a new chemical that is patent-eligible, the act of cre-

ating it will likely be obvious," he says. "So cDNA may not end up being the subject of valid patents after all."