Knobbe Martens
INTELLECTUAL PROPERTY LAW

IP FOR A NEW AGE®

# Federal Circuit Review

VOLUME 3 | ISSUE 7 JULY 2013

## Isolated DNA not Patent Eligible

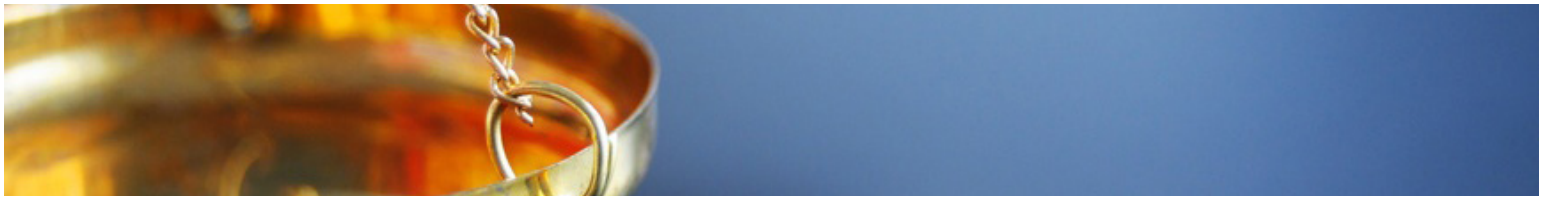
In ***Association For Molecular Pathology v. Myriad Genetics, Inc.***, No. 12-398, the Supreme Court affirmed in part and reversed in part the Federal Circuit's opinion which, on remand, had found both isolated DNA and cDNA patent eligible.

Respondent Myriad Genetics, Inc. (Myriad) obtained several patents after discovering the precise location and sequence of the BRCA1 and BRCA2 genes. Petitioners filed suit seeking a declaration that Myriad's patents were invalid under 35 U.S.C. §101. The district court granted summary judgment to Petitioners, concluding that Myriad's claims were invalid because they covered products of nature. The Federal Circuit initially reversed, but on remand in light of *Mayo Collaborate Services v. Prometheus Laboratories, Inc.*, it ultimately found both isolated DNA and cDNA patent eligible.

The Supreme Court affirmed in part and reversed in part, finding that a naturally occurring deoxyribonucleic acid (DNA) segment is a product of nature and not patent eligible merely because it has been isolated, but that complementary DNA (cDNA) is patent eligible because it is not naturally occurring. Myriad's DNA claims fall within the law-of-nature exception to patentable subject matter under §101. The location and order of the nucleotides existed in nature before Myriad found them. Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes. Myriad did not create or alter the genetic information encoded in the BRCA1 and BRCA2 genes. Finding the location of the BRCA1 and BRCA2 genes did not render the genes patent-eligible "new… compositions of matter" under §101. The fact that isolating DNA from the human genome severs the chemical bonds that bind gene molecules together does not render Myriad's claims patentable as the claims are not expressed in terms of chemical composition, nor do they rely on the chemical changes resulting from the isolation of a particular DNA section. Instead, the claims focus on the genetic information encoded in the BRCA1 and BRCA2 genes.

Myriad's patents would have given it the exclusive right to isolate an individual's naturally occurring BRCA1 and BRCA2 genes, which is necessary to conduct genetic testing. The Court differentiated between naturally occurring DNA and synthetically created cDNA, which contains the same protein-coding information found in a segment of natural DNA, but omits portions within the DNA segment that do not code for proteins. cDNA does not present the same obstacle to patentability as naturally occurring, isolated DNA segments. Creation of a cDNA sequence results in an exons-only molecule that is not naturally occurring. The lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result,

### In This Issue



cDNA is not a "product of nature" and is patent eligible under §101.

The Court expressed no opinion regarding method claims, new applications of knowledge about the BRCA1 and BRCA2 genes, or the patentability of DNA in which the order of naturally occurring nucleotides has been altered, noting that such issues are not implicated by its decision. The Court also noted that it expressed no opinion on whether cDNA satisfies the other statutory requirements of patentability.

## Appeals Before Damages and Willfulness Determination OK

In ***Robert Bosch, LLC v. Pylon Manufacturing Corp.***, Appeal No. 11-1363, the en banc Federal Circuit found that 28 U.S.C. § 1292(c)(2) confers jurisdiction on the court to hear appeals from patent infringement liability determinations when issues of damages and willfulness remain.

In a patent infringement case, the district court stayed discovery related to damages and willfulness. After the trial on liability, the district court entered judgment and the parties appealed. Bosch then filed a motion to dismiss the appeals, arguing that the Federal Circuit lacked jurisdiction because issues of damages and willfulness were still outstanding. Following oral argument before a Federal Circuit panel, the court granted an en banc rehearing sua sponte to decide whether it had jurisdiction.

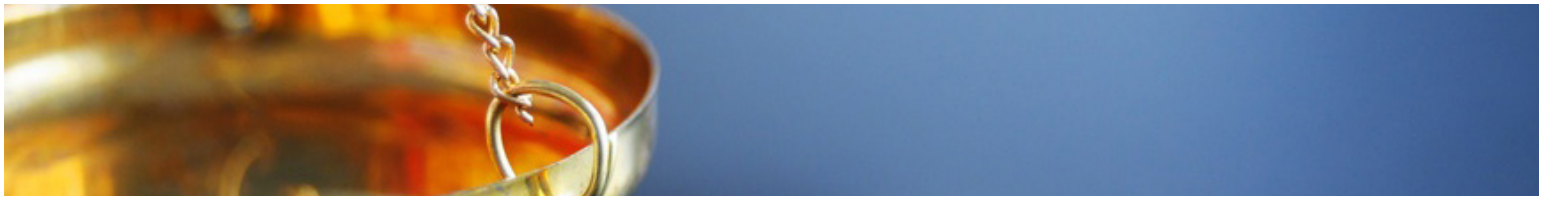
Jurisdiction before the Federal Circuit is governed by the final judgment rule. Under the final judgment rule, a party may not take an appeal "until there has been a decision by the district court that ends the litigation on the merits and leaves nothing for the court to do but execute the judgment." Section 1292(c)(2) creates a limited exception allowing the Federal Circuit to entertain appeals in patent infringement cases, which would otherwise be appealable and are "final except for an accounting." The court found that whether it had jurisdiction turned on the meaning of "accounting." Thus, the court considered the historical meaning, case law, and legislative history of the term and held that it had jurisdiction because "accounting" may include a trial on damages or a determination of willfulness.

## Reverse-Payment Settlement Agreements May be Invalid

In ***FTC V. Actavis, Inc.***, Appeal No. 12-416, the Supreme Court reversed and remanded the Eleventh Circuit's affirmance of the district court's dismissal of an FTC complaint for violation of Section 5 of the Federal Trade Commission Act.

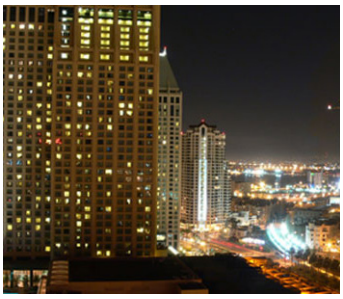
The FTC had filed suit alleging that a "reverse payment" settlement agreement between generic drug manufacturers and Solvay Pharmaceuticals, a brand-name drug manufacturer, unreasonably restricted competition in violation of the antitrust laws. In a reverse payment agreement, a brand-name drug manufacturer pays generic manufacturers to refrain from launching a generic version of the drug. The district court dismissed the FTC's complaint and the Eleventh Circuit affirmed, finding that Solvay's patent, if valid and infringed, provided a lawful monopoly that would have permitted Solvay to charge drug prices sufficient to recoup the reverse settlement payments it agreed to make to its potential generic competitors.

In reversing the appellate court, the Supreme Court stressed that the Solvay patent may or may not be valid. Moreover, commercial activity conducted within the scope of a valid patent has been held to violate antitrust law. The Court therefore held that the propriety of a reverse-payment settlement agreement must be assessed in view of the policies underlying the antitrust laws, not just the policies underlying the patent laws. The Court further held that reverse-payment settlement agreements, while not presumptively anticompetitive, could have anticompetitive effects and thus must be substantively evaluated under the rule of reason standard. Accordingly, the Court reversed the judgment and remanded the case to the Eleventh Circuit.



## Knobbe Martens Offices

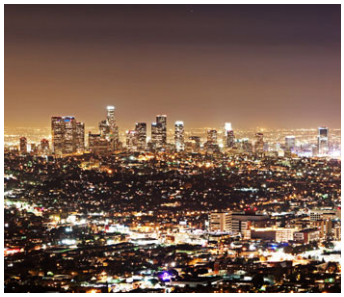
Orange County



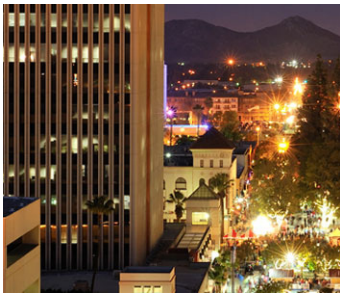
San Diego

San Francisco

Silicon Valley

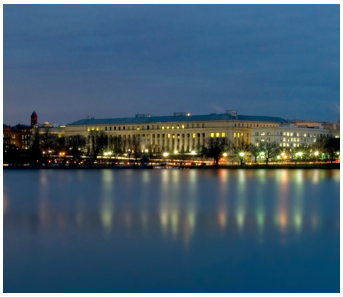


Los Angeles



Riverside

Seattle



Washington DC



## Who We Are

Over 95% of our litigators hold technical degrees, including electrical engineering, computer science, mechanical engineering, chemistry, chemical engineering, biochemistry, biology, and physics. Many of our litigators are former Federal Circuit or district court clerks. With eight offices, Knobbe Martens represents clients in all areas of intellectual property law.

- Exclusive practice in the area of intellectual property since 1962
- More than 250 lawyers, many of whom have advanced degrees in various technologies
- Internationally recognized leaders in IP across a vast spectrum of technology areas