

Washington Roundup

Supremes to Hear Arguments On 'Fraud-on-the-Market' Claims

By Marie Powers
Staff Writer

On Monday morning, the Supreme Court is expected to hear oral arguments in *Amgen Inc. v. Connecticut Retirement Plans and Trust Funds*, in which the big biotech is appealing a decision from the Court of Appeals for the Ninth Circuit that upheld a federal district court's refusal to hear evidence rebutting fraud-on-the-market claims involving erythropoietins before it certified a class in the shareholder lawsuit. (See *BioWorld Today*, June 12, 2012.)

The case pits the biotech industry – and, in a larger context, big business – against increasingly litigious shareholder groups. If courts can certify class actions without considering materiality evidence, it would lead to an automatic certification of all alleged fraud-on-the-market shareholder suits. Conversely, if the Supreme Court decides materiality should be considered as part of class certification, industry would have a potent weapon to defend against shareholder suits.

The fundamental premise of a fraud-on-the-market case is that a misrepresentation distorted the stock price, despite the fact that no individual investor is actually defrauded by the statements. The theory is that the market as a whole was defrauded, so shareholders should be certified as a class and allowed to bring a class-action suit against the company.

Numerous organizations have filed briefs supporting Amgen's case, including the Washington Legal Foundation, the U.S. Chamber of Commerce, the Securities Industry and Financial Markets Association, former Securities and Exchange Commission officials and groups of law professors.

The National Association of Shareholder and Consumer Attorneys, AARP, the New York City Pension Funds, the California Public Employees' Retirement System, Public Citizen and a group of financial economists filed briefs supporting the Connecticut Retirement Plans.

In purely legal terms, the case affects all industries, said

Stock Movers

10/2/12

Company	Stock Change	
Nasdaq Biotechnology	-\$31.38	-2.25%
Anthera Pharmaceuticals Inc.	+\$0.13	+13.54%
Corcept Therapeutics Inc.	-\$0.29	-12.90%
Dendreon Corp.	+\$0.62	+16.10%
Endocyte Inc.	-\$1.30	-14.05%
Soligenix Inc.	-\$0.14	-23.38%
Threshold Pharmaceuticals Inc.	+\$0.38	+9.27%
Vertex Pharmaceuticals Inc.	-\$5.47	-10.84%

(Biotechs showing significant stock changes Friday)

Cory Andrews, senior litigation counsel at the Washington Legal Foundation.

"Certainly, those biotech entities that find themselves on the wrong end of a class action or securities fraud suit will have interest in the outcome of the case, but the legal precedent that it sets will be much broader," Andrews told *BioWorld Today*.

Arguments are likely to focus on the particular questions courts are obliged to answer at the certification stage and at the merits stage, he said. Once a class is certified, plaintiffs have enormous leverage to force a settlement, even in a case where defendants are convinced no wrongdoing occurred.

Although the class-action device is designed to be efficient and conserve judicial resources, "in this case, we think efficiency favors the position taken by Amgen, which asked to be able to present at an early stage in litigation a defense that, if established, would negate the entire lawsuit," Andrews explained. "I can't think of anything more efficient than that."

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The case could provide the high court an opportunity to give any class-action defendant, especially those facing a securities fraud class-action suit, “an opportunity to clear its name at the earliest possible stage in the litigation,” he added. In their questioning, the Supremes could refer to a 2011 decision in *Walmart v. Dukes* “that just because issues overlap with the merits of the underlying claim doesn’t mean those issues shouldn’t be taken up at the certification stage,” Andrews said.

CRS Report Examines BioShield Effectiveness

Three congressional bills may affect the governance of the Project BioShield Act (P.L. 108-276), passed by Congress in 2004 to provide the federal government with expanded authorities to develop, procure and use medical countermeasures against chemical, biological, radiological and nuclear (CBRN) terrorism agents. (See *BioWorld Today*, May 20, 2004.)

Project BioShield provides three main authorities: guaranteeing a federal market for new CBRN medical countermeasures; permitting emergency use of countermeasures that are either unapproved or have not been approved for the intended emergency use; and relaxing regulatory requirements for some CBRN terrorism-related spending. The Department of Health and Human Services (HHS) has used each of those authorities, obligating some \$2.625 billion to guarantee a government market for countermeasures against anthrax, botulism, radiation exposure and smallpox. HHS also allowed the emergency use of several unapproved products, most recently during the 2009 H1N1 influenza pandemic, and used expedited review to approve contracts and grants related to CBRN countermeasure research and development. (See *BioWorld Today*, April 29, 2009.)

But some observers, including members of Congress, are considering whether the authorities have sufficiently contributed to national preparedness to merit extension. (See *BioWorld Today*, Sept. 12, 2011.)

A recent Congressional Research Service (CRS) report examined the options under consideration by Congress as the expiration of some of those authorities approaches. Policy questions include whether the Project BioShield acquisition mechanism merits extension based on its relative cost and contribution to national preparedness. If so, congressional policymakers may consider whether changes to funding levels or how Congress provides Project BioShield funds would improve the program’s efficiency or performance.

Additionally, congressional policymakers are considering whether the federal government sufficiently plans and coordinates its CBRN countermeasure efforts from basic research to distribution. Finally, Congress is considering whether changes to the emergency use

authority will improve preparedness and planning.

Two bills in the 112th Congress – the Pandemic and All-Hazards Preparedness Reauthorization Act of 2011 (H.R. 2405, passed the House on Dec. 6, 2011) and the Pandemic and All-Hazards Preparedness Act Reauthorization of 2011 (S. 1855, passed the Senate on March 7, 2012) – would extend the Project BioShield acquisition authority, though lawmakers would still need to address the amount and length of additional funding. That legislation could potentially address broader countermeasure development issues, according to CRS, including risk assessment, strategic planning, countermeasure prioritization, basic research, countermeasure approval and countermeasure distribution.

A third bill, the WMD Prevention and Preparedness Act of 2011 (H.R. 2356, reported by the House Committee on Homeland Security on Sept. 12), would change the countermeasure development and acquisition process by creating a White House position to coordinate federal biodefense policy and requiring formal planning activities and reporting.

That bill would require the president to appoint a special assistant for biodefense, who would be the principal national advisor on coordinating federal biodefense policy, lead the development of federal biodefense-related plans and conduct oversight and evaluation of federal biodefense activities. The bill also would require the Department of Homeland Security (DHS) to review the CBRN agents that were previously determined to pose a material threat to national security and assess whether they continue to do so.

Such a reassessment could result in some countermeasures becoming excluded from Project BioShield – a potentially devastating hit on biotechs developing therapies against anthrax, Ebola, radiation sickness and other medical countermeasures. That list of firms has grown extensively over the past decade, including companies such as PharmAthene Inc., Cleveland BioLabs Inc., Aeolus Pharmaceuticals Inc., AVI BioPharma Inc., Elusys Therapeutics Inc., Emergent BioSolutions Inc. and Cellarent Therapeutics Inc.

Final Rule on Physician, Hospital Payments

The Centers for Medicare & Medicaid Services issued a final rule on physician fee payments and hospital payments. The physician final rule addresses changes to the physician fee schedule, payments for Part B drugs and other Medicare Part B payment policies and implements provisions of the Affordable Care Act by establishing a face-to-face encounter as a condition of payment for certain durable medical equipment items. The hospital final rule revises the Medicare hospital outpatient prospective payment system and Medicare ambulatory surgical center payment system for CY 2013.

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Both rules, which have 60-day comment periods, go into effect Jan. 1, 2013.

Mechanism of Action for Chemotherapy Class

Researchers at the National Institutes of Health (NIH) discovered a new mechanism of action for a class of chemotherapy drugs known as poly (ADP-ribose) polymerase inhibitors, or PARP inhibitors. They also identified differences in the toxic capabilities of three drugs in this class that are currently being investigated in clinical trials.

In recent years, PARP inhibitors have demonstrated promise as cancer agents in breast and ovarian cancer. Members of the PARP family of proteins are involved in a number of critical cellular processes, including DNA damage repair and programmed cell death. Prior to the study, PARP inhibitors were thought to work primarily by blocking PARP enzyme activity, thus preventing the repair of DNA damage and ultimately causing cell death. In the NIH-sponsored study, scientists established that PARP inhibitors have an additional mode of action: localizing PARP proteins at sites of DNA damage, which has relevance to their antitumor activity. The trapped PARP protein-DNA complexes are highly toxic to cells because they block DNA replication.

The study, by scientists at the National Cancer Institute, and colleagues, appeared in *Cancer Research*. ■

Financings Roundup

- **Isonova AB**, of Uppsala, Sweden, carried out a fully subscribed rights issue of about SEK50 million (US\$7.4 million) to finance clinical trials in-house,

increase production capacity and continue research in new indications for the adjuvant Matrix M. Shareholders representing 46.3 percent committed to subscribe for their respective pro rata share of the issue, with the remainder guaranteed by a consortium.

Clinic Roundup

- **Genkyotex SA**, of Geneva, said Phase I studies demonstrated safety and tolerability following single and multiple oral doses of GKT137831, a NOX 1 and 4 inhibitor. The drug also demonstrated a favorable pharmacokinetic profile. Genkyotex is developing GKT137831 for oxygen-radical mediated diseases.

- **TransTech Pharma Inc.**, of High Point, N.C., said recruitment for its recently initiated Phase III trial with TTP054 in Type II diabetics is exceeding expectations with initial top-line results to be available in early 2013. The 90-day proof-of-concept study is being conducted in diabetics not well controlled with approved oral agents. TTP054 is designed to act as an agonist of the glucagon-like peptide 1 receptor.

Pharma: Other News To Note

- **Bristol-Myers Squibb Co.**, of New York, said the National Institute of Health and Clinical Excellence decided to recommend Yervoy (ipilimumab), which is approved in Europe for treating advanced metastatic melanoma, within the final appraisal determination. That decision will enable eligible patients in England and Wales to routinely access treatment with Yervoy through the National Health Services.

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