BOTM: January 2009

Biomaterials Availability and Policy SIG

Presentations and Discussions – At the SFB Meeting in Buckhead/Atlanta, GA, our SIG sponsored a well received panel discussion "Changes in Biomaterials Unavailability, Patents, Product Liability, Tort Reform and the FDA" co-chaired by Carl McMillin and Jim Curtis. A summary of some of this information (partially presented below) will be reviewed at the *Orthopaedic Manufacturing & Technology Exposition and Conference, OMTEC 2009*, in Rosemont, IL on June 24, 2009 by Carl McMillin.

Biomaterials Unavailability & Availability News – At the World Biomaterials Congress in Amsterdam, it was announced that Royal DSM N.V (makers of Dyneema linear PE fiber) has acquired The Polymer Technology Group (PTG) (with their wide selection of implantable polyurethanes). PTG is now part of DSM Biomedical and is know as DSM PTG with headquarters in Berkeley, CA. This should improve the access of small companies to several additional biomaterials.
The Tecoflex family of polyurethanes, currently sold by Lubrizol Advanced Materials, has expanded since on December 31, 2008 Lubrizol acquired Dow Chemical Company's Pellethane and Isoplast polyurethanes to expand its medical applications.
In the implantable poly(aryl ether ketone) arena, Evonik/Degussa now sells Vestakeep PEEK, and Solvay Advanced Polymers now sells Zeniva PEEK in addition to Oxford Performance Materials OXPEKK and Invibio's Optima PEEK.
Solvay Advanced Polymers has also introduced in its Solviva line of implantable grades of polymers which includes Proniva, a self-reinforced polyphenylene and Veriva, a polyphenylsulfone Veriva.
With several multinational polymer companies now selling materials suitable for implants, 2008 was a banner year.

Changes in Product Liability – In case you have been living in a cave recently, the Supreme Court decided in February 2008 in *Riegal v. Medtronic* that the preemption clause of the *Medical Device Amendments of 1976* bars common-law claims challenging the safety and labeling of medical devices approved via the PreMarket Approval (PMA) process. In this case, Charles and Donna Riegel unsuccessfully sued Medtronic after one of their balloon catheter devices burst during angioplasty requiring advanced life support and emergency coronary bypass surgery.
After the Supreme Court ruling on Federal Preemption, lower courts have started dismissing similar cases. These include a class action lawsuit of thousands of patients in a federal case in Minneapolis related to the Sprint Fidelis defibrillator of Medtronic that was recalled after a number of wires fractured and a state lawsuit in Colorado related to squeaky Trident ceramic-on-ceramic artificial hips from Stryker. Future items to watch include the Supreme Court case of Wyeth v. Levine filed in November 2008 on drug labeling that will determine whether drugs get the same preemption accorded to devices.
On the other hand, Senate Bill 3398 was introduced in June 2008 by Senator Kennedy (with 15 co-sponsors including now President Barack Obama and now Secretary of State Hillary Clinton) which would amend the Federal Food, Drug, and Cosmetic Act to eliminate the liability preemption. A similar bill H.R. 6381 was introduced into the House of Representatives. Although nothing happened last year, with a new Congress and new President, we will have to wait and see what develops.

Changes in Patent Law – Again, no major bill passed in the 110th Congress on patents, but various bills introduced proposed major changes in patent law, including a switch from first-to-invent to a first-to-file system (like much of the rest of the world), substantial changes to patent infringement damages, and limitations on the selection of courts for patent litigation. The new 111th United State Congress will last from January 3, 2009, until January 3, 2011.