SurFACTS in Biomaterials

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Excellence in Surface Science Award Winner: Gabor Somorjai

By Keith McCrea

A surface is just the truncation of the bulk; if you know the bulk structure you will then know the surface structure. At least, that was the general assumption before Professor Gabor Somorjai pioneered modern surface science. Like many areas of new science, progress had to not just wait for the development of technology, but also for a visionary to apply it to a new frontier of study. Somorjai has been such a visionary throughout his career, from studying surfaces under ultra high vacuum in the 1960s to studying surfaces under high pressure or in solution since the 1990s. Now, we understand that surfaces are very dynamic, from metals to polymers, in the way they respond to minimize interfacial free energy.

Gabor Somorjai, considered by many to be the father of modern surface chemistry, is the winner of the 2009 Surface Science Award of the Surfaces in Biomaterials Foundation. His pioneering work laid the foundation that is currently at the heart of biomaterial surface analysis. Ultra-high vacuum (UHV) techniques such as x-ray photoelectron spectroscopy (XPS) are used widely to study the atomic structure of biomaterial surfaces, while high pressure techniques such as sum frequency generation (SFG), scanning tunneling microscopy (STM), and atomic force microscopy (AFM) to study surfaces under high-pressure or buried surfaces such as the solid/liquid interface. Somorjai has graduated over 120 Ph.D. students and mentored over 250 post docs throughout his career. His research group has been prolific, publishing over 1000 journal articles and Somorjai

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From the Editor

In the March-April 2009 SurFACTS, I addressed governmental support of small business R&D funding through the Small Business Innovation Research and Small Business Technology Transfer programs (SBIR and STTR). In the May-June issue I provided a follow-up on the status of the reauthorization of the SBIR/STTR programs, and a more detailed discussion of the American Recovery & Reinvestment Act (ARRA) grants. In this editorial, I will keep my comments brief, since the column by Kim Hart of The Washington Post provides a complementary and important perspective (page 6).

As a very brief background, the SBIR/STTR programs are funded by a governmental set-aside of a small percentage of research grants from all US government agencies that provide grant funding. Relevant to our disciplines, this includes the NIH (National Institutes of Health), the NSF (National Science Foundation) and the DoD (Department of Defense). The SBIR/STTR program has been ongoing since 1982, and currently (for another month) requires that 2.8% of external granting from most federal granting agencies be directed to small businesses, rather than to other, mostly academic, recipients. The SBIR/STTR grants program has been extremely valuable to the medical device as well as other high-tech industries, including, as I tracked in the May-June SurFACTS, at least $16 million in R&D support to our member companies.

So, why am I addressing this issue again? Two-fold. First, I am steamed that a substantial portion of ARRA funds allocated to the NIH were subverted from being effectively utilized to support small business technology development. Second, it is

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By Steven L. Goodman, Ph.D., 10H Technology Corporation

about time that the SBIR and STTR programs be reauthorized and provided with adequate funding.

These issues are very nicely addressed by Hart's Washington Post column (page 6). She points out that when NIH received $10B in ARRA stimulus funding, at the last minute there was a change in the legislation so that NIH was no longer obligated to set aside the "usual 2.8% percentage" to small business. (This would have been about $280M, or enough to support 280 start-up companies for 1-2 years—talk about a jobs program!) Instead, the first ARRA program created by NIH was the Challenge Grants program, and this program was opened up for small business to apply along with academics. To anyone, like myself, who has experience as both an academic and a small business entrepreneur, and who has served on numerous NIH grant proposal review panels, this is totally unreasonable. A small business proposal from "two guys and a garage," or even from a small business with a dozen or more employees and a small lab in a research park, simply cannot compete against even a small university. Even with a brilliant idea and proof of principle, I can't tell you how many times I have seen review panel members downgrade a small business proposal because the company doesn't have the laboratory or instrumentation infrastructure. A typical review comment is, "The Company has minimal facilities and outsources all their major instrumentation work to contract labs." In reality, this is as it should be. Small companies should always equip their labs with only just what they absolutely need, and should not purchase instruments without a thorough cost-benefit analysis. Moreover, those of you in large companies know that this is the case in your firm as well. Why purchase an SEM or a fluorescence microscope, not to mention the really expensive instruments such as a confocal, a SIMS, or hire a staff pathologist, when these can be outsourced? This is simply smart business. But, a major university has all this, and because reviews are skewed toward academic criteria, the standards of what is acceptable prevent small business from successfully competing. A second area where small businesses can't compete when academic criteria are used is exemplified in the following common review comment: "While the principal investigator has 20 years experience at (pick one of our member companies), and has successfully brought several new medical devices to market, she has apparently not published in 20 years." The playing field is simply not level since, at best, only very few reviewers have industrial experience, so they don't understand that in industry the goal is not to publish but to bring products to market and sell them. Since funding priorities are determined by numerically averaged scores, even if some of the reviewers understand this, is often not enough.

Hart clearly points out that small businesses are not only unprepared to compete for grants against academic institutions, but that preparing a grant proposal is a major undertaking for a small business. As a consultant, it is obvious to me that most industry engineers or scientists have never done this type of writing, or certainly not since they were in graduate school. Moreover, businesses must always balance their effort. For a company it comes down to the question of, "Should I spend 80 or more hours to prepare a proposal for a 10-20% chance of funding, or should I invest my time in another business activity?" While there is real intrinsic value in preparing a solid proposal, including a careful evaluation of your business, your market, your competition, and the development of a very detailed R&D, plan, there is also only a minimal probability

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SurFACTS in Biomaterials is the official publication of the foundation and is dedicated to serving industrial engineers, research scientists, and academicians working in the field of biomaterials, biomedical devices, or diagnostic research.

Team Develops Anti-Infection Technology

PRNewswire - SOURCE West Virginia University Health Sciences Center

Combat-related injuries have long plagued the military in part because of multidrug-resistant bacteria. Imagine being able to spray a compound fracture with microcapsules that deliver a drug to bolster the immune system, stopping infection before it starts.

That technology might be around the corner, says Bingyun Li, Ph.D., of the West Virginia University Department of Orthopaedics and director of the WVU Biomaterials, Bioengineering & Nanotechnology Laboratory. Li's team has developed a drug-delivery technology involving microcapsules—and a second technique, nanocoating—that have been shown to work in animal studies.

Results of the team's research involving the drug interleukin-12, a drug currently in anti-cancer clinical trials, have been published in the May issue of the journal *Biomaterials*. A deeper explanation of the approach, which could develop into an alternative to antibiotic therapy, is scheduled to be published in an upcoming issue of the *Journal of Orthopaedic Research*.

"These pioneering techniques could be important to the United States because of the wars in Iraq and Afghanistan," Li says. "The treatment of battlefield casualties is expensive, and the infection rate runs from 2 percent to 15 percent. In some cases, because the organisms have developed resistance, antibiotics don't work."

Outside the arena of warfare, millions of people could potentially be helped by the technology because infections can result whenever a biomedical device is implanted.

Li's team developed two ways to deliver interleukin-12. The first is in microcapsules that can be injected or, potentially, delivered in a fine-mist spray directly to the site of an injury. The second is a nanocoating of interleukin-12 applied directly to stents, pacemakers, pain pumps, artificial limbs—virtually any biomedical device—before implantation.

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there is also only a minimal probability for a direct cash payoff. When the funding probability is lowered to less than 1%, as it was in the recent Challenge Grant ARRA program, then there is a problem.

Finally, the whole concept of the ARRA funding was and is to generate jobs! Small business is the largest source of current and future potential jobs. Thus, not providing a mechanism to fund small businesses substantially subverted the intent of the ARRA funds when small business is the veritable fountain of employment in general, and for scientists and engineers in particular. According to the Small Business Technology council, "U.S. small businesses employ more scientists and engineers than large businesses (32 percent vs. 27 percent), and more than universities and federal labs combined (32 percent vs. 29 percent)." And the Council goes on to point out that much less federal R&D funding goes to small businesses, which receive, "only 4.3 percent of Federal R&D funds, while larger firms receive 50.3 percent and universities and colleges receive 35.3 percent." Our governmental funding to create jobs should go where it is most effective, and currently it does not.

I doubt that much can be done with the American Recovery & Reinvestment Act not supporting small businesses, at least through NIH. The ARRA funded NIH BRDG-SPAN program (see NIH website and/or my May-June editorial) will hopefully function much better in this regard than the last Challenge grant program. But ARRA funding is short term, while the SBIR/STTR program has been a long-term highly successful program.

So, what is the current status of the SBIR/STTR program? Well, little has changed since I drafted the May-June editorial. There are substantial differences between the SBIR/STTR reauthorization bills in the House (HR 2965) and Senate (S 1233), and these need to be reconciled. As I draft this editorial, both the Senate and the House have passed a Continuing Resolution to keep the current SBIR/STTR program going for the very short term—until September 30, 2009. Thus, there is still time to contact your representatives to let them know how critical this issue is for the biomaterials and medical device community.

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has written three textbooks. Additionally, many of Somorjai's past graduate students and post docs have continued their careers studying biointerfaces. "Gabor Somorjai is a giant in the field of surface science and catalysis. He has beautifully led the way in the field of biomaterial interfaces in particular. Most importantly he has clearly shown that molecular level mechanisms can be solved on these complex surfaces. He has also charged ahead in the development of new instrumentation for this field," says former Somorjai graduate student, Professor Paul Cremer from Texas A&M.

Somorjai has won many awards throughout the years including the Priestly Medal, Wolf Foundation Prize, and the National Medal of Science. In 1979, he was elected to the National Academy of Sciences and was named a University Professor by the UC Board of Regents.

Not only has Somorjai solved many technical and scientific challenges throughout his career, but early in his life, he had to overcome hurdles just to survive. Born in Hungary in 1935 of Jewish descent, his family escaped Nazi death camps during World War II. While he, his mother, and sister were saved by the Swedish diplomat Raoul Wallenberg by seeking refuge in one of the houses under Swedish protection, his father was forced into the Hungarian Army and later sent to the Mauthausen Concentration Camp. Against all odds, Somorjai's father survived the death camp and returned to the family after the War. In 1953, Somorjai was accepted into the Technical University in Budapest and began studying chemical engineering with 200 other first year students. They were all vying to be one of 50 students who would be allowed to graduate under the planned socialist economy. It was during his time at the University that Somorjai met and started dating Judith Kaldor, who would later become his wife. During the fall of 1956, just a few months before graduation, the Hungarian Revolution broke out, in which many university students were active participants. When Communist Russia reoccupied the city, Somorjai and Judith escaped to Austria, and later immigrated to the United States in January of 1957.

Once in the United States, they both enrolled in chemistry at the University of California at Berkeley and married shortly thereafter. It was in graduate school where Somorjai first started studying surfaces. He was interested in both catalysis and polymers and knew little about either. At the time, neither subject was being actively researched by Berkeley faculty. However, he joined Professor Richard Powell's group where Somorjai began studying platinum catalysts. In just three years, Somorjai finished his Ph.D. and was hired at IBM Research in New York during the winter of 1960. His time at IBM only reinforced his interest in surface science and he decided to seek a faculty position.

In July of 1964, Somorjai joined the faculty at UC Berkeley and continued his research on platinum catalysts. He knew that studying supported catalyst systems would be very challenging, especially with the limited instrumentation at the time. Therefore, he decided to work on platinum single crystals to serve as a model system, a successful strategy that has been repeated many times. Somorjai used UHV techniques such as low energy electron spectroscopy (LEED) and Auger electron spectroscopy to study these surfaces. Using these tools, he was the first to show that the surface structure of metal was not simply represented by truncating the bulk structure. He showed that atomic packing on the Pt(100) surface was hexagonal, not the expected square structure. Such observations have since been made on many other single crystal surfaces. The idea that clean surfaces reconstructed had a huge impact on surface science. After careful characterization of clean surfaces, Somorjai then started characterizing adsorption of organic molecules on single crystal surfaces. He was able to determine precise bond distances and bond angles of organic monolayers, and was also able to show that these adsorbates could impact the underlying surface structure of the metal below. From his work on catalysis, Somorjai coined the idea of "Flexible Surface" due to the ability of surface atoms on catalysts to respond and restructure to allow chemistry to happen.

As surface science grew, Somorjai always looked for new techniques to apply, such as SFG and STM,

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which could study interfaces in situ. Continuing his research in catalysis, Somorjai was able to identify intermediate and spectator molecules during catalytic reactions. He continues to study catalytic systems under high-pressure and is also investigating nano-particles.

Somorjai has always been interested in biological interfaces. In the mid 1990s, he was applying SFG to study high-pressure catalysis when he began collaborating with The Polymer Technology Group (PTG) in Berkeley (now known as DSM PTG). Somorjai applied SFG and AFM to studying the molecular surface structure of medical grade implantable materials. These studies looked at surface reconstruction as a material was exposed to a hydrated environment and effects of mechanical stress, such as stretching. Robert Ward, a previous winner of the Surface Science Award of the Surfaces in Biomaterials Foundation, reflects that significant innovation in surface modification at DSM PTG was due to this collaboration. "I have been interested in surface activity and self assembly in polymers since the mid 1970s and I've used just about every available surface analytical method to study it. All of them had shortcomings like the need for high vacuum and/or the fact that they looked too deeply into the bulk.

"After 20 years of work I met Gabor who introduced me to SFG. All of a sudden, surface chemistry got easy because we could easily determine composition and orientation in the outermost molecular layer under conditions relevant to biomaterials. SFG correlated beautifully with work we had done with contact angles, but gave much more information. This led to our development of Self Assembling Monolayer End Groups (SAME™) and their use in the modification of biomedical polymer surfaces for a wide range of medical devices." As with metal surfaces, it would be appropriate to consider a polymer to also have a "flexible surface" due to its ability to respond to environmental stresses to lower the interfacial free-energy. This has tremendous impact on choice of materials for medical device design.

Somorjai is continuing to lead in characterization of biointerfaces and is currently studying model peptide adsorption on model hydrophobic and hydrophilic surfaces using SFG, AFM, and quartz crystal microbalance (QCM). He is also looking at fundamental adsorptions studies of amino acids on model surfaces. These studies, among the studies of other leaders in the field inspired by Somorjai's pioneering work, promise to help pave the way for characterizing much more complex surfaces and interfaces in the future.

ATS Medical Heart-Valve Product Implanted for First Time

By Kerry Grace Benn, Dow Jones Newswires

ATS Medical Inc. (ATSI) announced the first implant of its Simulus semi-rigid annuloplasty band, marking an alternative to heart-valve replacement.

The company got U.S. Food and Drug Administration approval for the band in May, although it repeated recently that the device had been cleared. Shares were recently up 16 percent at $3.85 in premarket trading.

Annuloplasty rings are used in cases where repair of a patient's heart valve is preferable to replacing the valve.

The company said its Simulus semi-rigid band is designed to allow for a more physiologic valve repair, as it permits the natural motion of the mitral annulus.

Dr. Robert Hebeler Jr., who performed the first implant of the band at a hospital in Texas, called the device "the next advancement in annuloplasty repair rings" and said it was an excellent option for patients with mitral valve regurgitations, in which the mitral valve doesn't close tightly, allowing blood to flow backward in the heart.

The band was developed through the company's partnership with Genesee BioMedical.

In May, when the company announced FDA approval of the band, Chief Executive Michael Dale said the company's valve-repair business continues to grow amid more offerings in flexible and semi-rigid products.

Start-Ups Say Innovation Doesn't Grow on Trees

By Kim Hart, The Washington Post

Biotechnology start-ups have long relied on grants from the National Institutes of Health to fund the research-and-development process for new drugs, medical devices and disease treatments. Every year, the agency is required by law to set aside 2.8 percent of its research budget —$650 million in 2009—for small businesses and the commercialization of technologies developed at universities.

But when nearly $10 billion in stimulus funds went to the NIH, a last-minute change in the legislation exempted the agency from the requirement. That means the NIH does not have an obligation to reserve a portion of the money to small businesses.

This has created a stir in the area's biotech community. The companies say that without the requirement to set aside money for the Small Business Innovation Research program, they have a tougher time securing funding that could help them develop new products and survive the recession.

"It has just been a slap in the face to small businesses, especially because it's been a lifeline to biotech," said Aprile Pilon of Clarassance, a Rockville-based biopharmaceutical company that develops treatments for respiratory diseases. "We don't have access to institutional investors. We're going to lose a lot."

The SBIR program has been a key part of the grant-giving process for many agencies that support research and development, including the Energy Department and the Agriculture Department. For biotech companies, the NIH grants typically help companies pay for clinical trials or move their products through the regulatory process. Universities and other academic institutions also receive a large number of grants for scientific research.

In February, executives from 20 companies sent a letter to Maryland's senators, Democrats Barbara A. Mikulski and Benjamin L Cardin, asking for help in applying the small-business set-aside to the stimulus funds. Recently, Cardin, Rep. Chris Van Hollen (D-Md.) and Rep. Donna F. Edwards (D-Md.) held a hearing in Rockville on the issue. Jonathan Cohen, chief executive of 20/20 Gene Systems, Joe Hernandez, chief executive of Innovative Biosensors, and Pilon testified before the panel.

Raynard Kington, acting NIH director, did not attend the hearing. Instead, Sally J. Rockey, director of extramural research, sent written testimony outlining alternative funding programs that did not reach the members of Congress until after the hearing. Cardin, Van Hollen and Edwards sent a pointed letter to Kington after the hearing, saying that his "absence sent a message of indifference."

In a subsequent interview, Rockey said no one was available to appear at the hearing. She also said that, although the NIH is not required to provide a set amount of funds for small businesses, the agency has encouraged them to apply for several other funding opportunities supported by stimulus money. These programs, she said, have received a lot of interest from biotech firms.

"When the Recovery Act was first being discussed, we were concerned, because the number of [small-business] applications had dropped dramatically," she said. "And we were concerned we wouldn't have enough applications to distribute funds expeditiously."

Pilon argues that small-business applications get tougher scrutiny than those from academic institutions, and she claims that the board reviewing the applications is largely made up of university representatives.

"Small businesses are at a disadvantage in terms of preparing grants," she said. "We don't have the resources that universities do. We have to think hard if we have the time and money to write a grant, and if we don't get grant funding, the penalty is much greater than if a university doesn't get funding."

Cha-Mei Tang, chief executive of Potomac-based Creatv MicroTech, said she recently submitted a

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grant application to help hire more employees to gather patient samples and statistics in the development of a tool to detect chronic lymphocytic leukemia. She said past efforts to compete for funds that are not reserved for small businesses have been unsuccessful, so she is concerned that companies will not have much of a shot at stimulus money.

"Everything we sell is based on SBIR funding," Tang said. She said she planned to visit lawmakers on Capitol Hill before the summer recess. The House was scheduled to take action to reauthorize the SBIR program, which expires at the end of July. The biggest issue in question is whether venture-backed firms should have access to SBIR grants.

Allen Cunningham, chief executive of Charlottesville-based Gencia, said his company received an NIH grant that is not tied to stimulus funding for the pre-clinical development of a therapy for Alzheimer's disease, so his company is not in dire need of additional money at the moment.

But he said he agrees that setting aside some portion of the stimulus funding would be invaluable for small firms. "There's no doubt that if the exemption wasn't there, that more money would be available for applicants and in line with the goals of the stimulus," he said.

Japanese Scientists Unveil Ultra-Thin Surgical Patch

From AFP

Japanese scientists said they had developed a surgical "nano-sheet" one thousand times thinner than cellophane that can patch up internal wounds and later dissolves inside the body. The transparent and adhesive sheeting, made from a substance derived from crab shells and a viscous gum from algae, is just 75 nanometers thick. A nanometer is one-billionth of one meter.

"This is the world's thinnest adhesive plaster," said Toshinori Fujie, a researcher involved in the joint project by Tokyo's private Waseda University and the National Defense Medical College.

"We know food cellophane clings on to the surface of various objects. We have made a sheet ultimately thin... so that it is highly flexible and can stick to organs well with no glue," he told ***AFP***.

Surgeons normally stitch or staple wounds, or they use sheets several millimeters thick coated with fibrin, a protein that makes blood clot and works like glue but which can cause unwanted sticking to nearby tissue. In an experiment repeated several times, the team placed a square piece of the new nano-sheet onto a six-millimeter-wide hole in a dog's lung.

The sheet was strong enough to withstand the pressure of the dog's breathing and helped the wounds heal within one month, leaving no visible trace, Fujie said.

Researchers hope to launch human clinical trials in three years. They may also expand the use of the sheets for external use.

"Organs repaired with this sheet do not have scars, unlike after stitches," Fujie said. "We believe this could also be true on the skin."

This would open the way for other applications, for example for surgery wounds in breast cancer patients, he said.

"Some people also want to use this for treating bed sores. The next application will definitely be on the skin," he said.

Fujie said the inventors were also thinking of other possibilities—including in cosmetic use, for example by stretching out wrinkles or holding in place skin conditioners.

"As this is transparent on the skin, you could be wearing a face pack while working in the office," he said.

Smith & Nephew CEO Sees Lasting Pressure on Orthopedics Market

By Jon Kamp, Dow Jones Newswires

The slowdown affecting the orthopedic-devices market is likely to continue for several months as people with bum knees and hips defer procedures due to economic uncertainty, according to the top official at Smith & Nephew PLC.

The U.K.-based company does about half its orthopedics business in the U.S., where lost health insurance, steep co-payments or worries about time off from work have slowed growth in procedures for replacement hips and knees. The industry in general is anticipating growth this year will be roughly a couple percentage points below the typical high single-digit pace of market expansion.

"That's pretty much what we've seen," said David Illingworth, Smith & Nephew's chief executive, in an interview with Dow Jones Newswires. "I think we're going to see a few more quarters of pressure on volumes," he added. "I don't think it's played out yet."

He also discussed the outlook for bone-sparing hip resurfacing technology in the U.S., where market growth has been restrained amid thin competition, and the rising need for medical evidence to defend premium-priced products as the U.S. pursues health reform.

Smith & Nephew competes in the $11 billion hip and knee market with Zimmer Holdings Inc., Johnson & Johnson, Stryker Corp. and privately held Biomet Inc. Though a smaller player among this group, Smith & Nephew is the biggest European medical-devices company.

Illingworth, who didn't talk specifically about the second quarter, stressed that he believes orthopedic procedures are being pushed back rather than cancelled altogether. People typically need joint-replacement surgery to fix painful arthritic problems that can worsen while they wait.

"I really don't think that we're ultimately going to lose those procedures," he said. "I think it's people saying 'look, there's uncertainty in my life and this is not the time to be going and taking three months off of work and getting a knee replaced.'"

Illingworth said the company hasn't seen anything remarkable regarding product prices, which are holding ground. The company is watching, however, for any signs that premium-priced products are coming under pressure in this economic environment, he said.

The CEO also met with sell-side analysts during a U.S. visit, and left Wachovia's Michael Matson saying that while the orthopedics markets may be close to a bottom, "a rebound does not appear imminent."

Pressure on product prices is an ever-present concern in orthopedics, where companies often rely on fetching premiums with new products to bolster their revenue growth. In a newly cost-conscious environment amid the push for U.S. health reform, orthopedics companies will need to show high-priced products also yield premium results, Illingworth said.

He pointed to a product (a model of which he had on hand) that is part of a knee-replacement system in which instruments are customized for patients. The company plans on premium prices, but believes it can demonstrate the devices will more than offset this by improving accuracy and saving time, Illingworth said. Asked whether hospitals have demanded such evidence in the past, Illingworth said it wasn't a focus among device manufacturers.

Smith & Nephew is well-known for its "hip resurfacing" system, which takes away less bone than traditional hip surgery and may appeal to younger patients who could need that bone for later fixes. Resurfacing constitutes about 8% of hip procedures in top markets overseas, but has only grabbed about half that much in the U.S.

Some U.S. surgeons are skeptical about the merits of resurfacing, which is challenging to perform, and analysts say the market hasn't matched expectations. But Illingworth said

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it's actually where Smith & Nephew thought it would be and will grow further when more competitors reach the U.S.

All major competitors sell the technology overseas, yet market against it in the U.S., according to Smith & Nephew, which holds about 80% of the U.S. resurfacing market. Only the U.K.'s Corin Group PLC (CRG.LN) has thus far joined Smith & Nephew here.

"The way for us to move penetration further along in the U.S. is to get more competition," Illingworth said. Among other companies, J&J and Biomet may be closest to reaching the U.S. with their own resurfacing systems.

DSM Biomedical Proprietary Polymers Help Customers, AxioMed and Sunshine Heart, Reach Commercial and Clinical Success

From Business Wire

DSM Biomedical, a global company serving the medtech and biotech industries and part of Royal DSM N.V., announced two customers, AxioMed Spine and Sunshine Heart, are celebrating commercial and clinical success of their medical devices made with proprietary DSM Biomedical polymers.

AxioMed(R) Spine Corp. has recently received CE Mark approval for its Freedom(R) Lumbar Disc, an elastomeric total spinal disc replacement device. The CE Mark clears AxioMed to introduce the medical device into the European Union market. Using a patented silicone-urethane copolymer under exclusive license from DSM Biomedical, AxioMed's lumbar disc is designed to replicate the natural function of a human disc. The Freedom(R) Lumbar Disc was developed and designed by AxioMed clinicians and experts in the fields of biomechanics, pathology, and spine surgery in combination with DSM Biomedical experts in polymer science and processing. The material characteristics of DSM Biomedical's polymer, in combination with AxioMed's implant design, provide three-dimensional motion that mimic the natural biomechanics of the spine.

"We believe our Freedom(R) disc may represent the next generation of technology for treating degenerative disc disease," said Patrick McBrayer, AxioMed's President and CEO. "The goal of our technology is to restore the natural function of the spine. DSM Biomedical's polymer is well-suited to this goal. Its viscoelastic properties allow for compression, rotation and translation, while simultaneously providing load transfer and damping."

Sunshine Heart Inc. recently announced that The Ohio State University Medical Center has successfully completed the first two implants of the Company's C-Pulse(TM) heart assist system under a 20-person clinical trial approved by the FDA. C-Pulse is designed as a non-blood contacting heart assist therapy for treating patients with moderate to severe heart failure, a condition in which the heart progressively loses its ability to efficiently pump blood throughout the body. The C-Pulse device, which must pulsate up to 750,000 times per week, is made with two DSM Biomedical polymers.

"We started working with DSM Biomedical on an exploratory development program, advanced to a manufacturing program, and in result have developed a very durable Cuff for the C-Pulse," said Donald Rohrbaugh, CEO of Sunshine Heart. "We are very pleased with the partnership that has developed between Sunshine Heart and DSM Biomedical."

"We are very happy to partner with these two emerging medtech companies," added Bob Ward, President and CEO of DSM PTG, a part of DSM Biomedical. "The major milestones achieved by AxioMed Spine and Sunshine Heart occur within one year of the acquisition of The Polymer Technology Group (PTG) by DSM. Today, the combined resources of the former PTG and DSM ensure continued investment in new technology for delivering biomedical materials that advance or enable the development of next-generation medical devices."

More Data Needed on Using Catheters for Heart Disorder Report

By Jon Kamp, Dow Jones Newswires

A U.S. government report found that more research is needed to determine the potential long-term benefits of using tissue-burning catheters to treat a common heart problem that represents a fast-growing market for medical-device companies.

Johnson & Johnson (JNJ), St. Jude Medical Inc. (STJ) and Medtronic Inc. (MDT) are among the competitors that either have or are establishing big businesses to treat atrial fibrillation with catheters. With an annual-growth profile of more than 15%, the market for addressing the heart-rhythm disorder has become very attractive to a sector looking to offset slower growth in other cardiology markets.

The growth has come, however, without deep evidence that using devices, rather than drugs, delivers favorable long-term results. The best method for treating the rhythm problem, which puts patients at risk for stroke, is among the top-priority targets for "comparative effectiveness" research called for by the Obama administration.

The new report examining evidence for device-based treatment came from the Agency for Healthcare Research and Quality. Looking at existing studies on radiofrequency ablation, in which heat delivered by catheters is used to burn tissue to cut off problematic electrical signals, the report found the procedure helps maintain normal heart rhythms for up to one year.

But the report found little evidence regarding long-term outcomes and said the impact of device-based treatment on avoiding strokes was unknown when compared with drugs. Additionally, there is thin evidence regarding the benefits of device treatment on quality of life, avoiding anti-coagulation medication or hospital readmissions, the report found.

"Radiofrequency holds promise for treating atrial fibrillation, but it is clear that more research is needed to demonstrate its potential long-term benefits," said Carolyn M. Clancy, director of the Agency for Healthcare Research and Quality, in a release. The agency is part of the U.S. Department of Health and Human Services.

"This report crystallizes the questions that researchers need to ask going forward," Clancy said.

The market for catheter-based treatment of atrial fibrillation took off without specific U.S. Food and Drug Administration approval because doctors can use devices cleared for other purposes in so-called off-label cases. J&J's Biosense Webster unit in February became the first company to win FDA approval to market catheter treatment specifically for the disorder based on results from a moderately sized study.

The industry has put money toward acquiring large-scale and long-term evidence to support use of the devices.

The Mayo Clinic announced that it had secured $48 million in grants from St. Jude, Biosense Webster and the National Heart, Lung, and Blood Institute for a major study on the matter. Called "Cabana," the study will include 3,000 patients to be monitored for years who will be treated with either catheters or drugs to control their heart rhythms. The study's main goal is to see whether catheters help reduce mortality, but it will also track several other measures of safety and effectiveness.

Atrial fibrillation is the most common type of arrhythmia, affecting more than 2.2 million Americans, and its prevalence increases with age, the Agency for Healthcare Research and Quality noted.

Synthes, Medical Device Maker, Accused of Improper Marketing

By Barry Meier, The New York Times

A medical device maker, Synthes Inc., and four of its executives were indicted on federal charges that they improperly promoted a bone filler for purposes not approved by the Food and Drug Administration, including encouraging its use in what prosecutors called "unauthorized" human trials.

The indictment, sought by the United States attorney in Philadelphia, is one of the strongest actions taken in recent years against a maker of

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drugs or medical devices. Federal prosecutors typically file civil lawsuits seeking fines for such infractions, rarely bringing criminal charges against corporate executives. "They put their profits ahead of responsible business practices and the truth," Michael L. Levy, the United States attorney, said in a statement.

Synthes, of West Chester, Pa., is the American subsidiary of a large multinational company of the same name in Solothurn, Switzerland. In a statement issued by the parent company, Synthes insisted that all actions it had taken in connection with the marketing of the product, Norian XR, were legal.

"As a global leader in the medical device industry, Synthes has a long reputation for setting the highest legal and ethical standards in the development and commercialization of medical products," the statement said.

Prosecutors charged Synthes and Norian Corporation with running an unauthorized trial of the bone filler in spinal procedures known as vertebroplasty and kyphoplasty. Three people died in those procedures, though federal prosecutors said that they could not prove that the Synthes product caused the deaths. Prosecutors estimated that 200 patients had the improper operations.

The four executives were charged with criminal misdemeanors involving the shipment of unapproved medical devices. Those charges carry a possible prison sentence of one year.

Vertebroplasty and kyphoplasty, which are similar, are used to repair spinal fractures. In each procedure, a cementlike material is injected into the fracture. One safety concern involves the possible escape of the bone filling material into a patient's system, creating blood clots. The Food and Drug Administration has received injury and death reports about such episodes and in 2002 issued a warning about the risks.

In the indictment, prosecutors charged that Synthes officials considered seeking permission in 2001 from the FDA to run a trial of the bone filler in back operations but rejected the idea. Instead, company officials approached selected doctors to do operations with the understanding that the company "would help them publish the clinical results," the indictment charges.

The filler was approved in 2002 by the FDA. for use in general bone repair, but regulators insisted that Synthes not promote its use for spinal procedures. By 2002, Synthes had received information from a researcher at the University of Washington who reported lab and animal tests showing that Norian bone filler could generate large blood clots if it escaped from bone, the indictment states.

Shortly afterward, executives considered alerting the sales force not to promote the bone filler for unapproved uses, but they decided not to do so, prosecutors charged. Instead, the device maker began to hold sessions for doctors on how to use the bone filler and was about to promote it more aggressively when the company received a report in 2004 about the death of a third patient, court papers state. The company, which never reported the patient deaths to the F.D.A., also misled an agency inspector, prosecutors charged.

Norian faces possible fines of $28 million, while Synthes, its parent, faces fines of $8 million.

The individuals charged are Michael B. Huggins, the president of the Synthes spinal division; Thomas E. Higgins, the company's senior vice president for global strategy; Richard E. Bohner, a vice president for operations; and John J. Walsh, a regulatory affairs executive.

A lawyer for Mr. Huggins, Adam Hoffinger, would not comment. Efforts to reach the other men were not successful.

Global Partnership with Stryker for Distribution of LiquiBand™ Products in Cranio-Maxillofacial Surgery

From Reuters

Advanced Medical Solutions Group plc (AIM: AMS), the global medical technology company, announced that it has entered into an agreement with Stryker Corporation for global marketing and distribution of certain of its LiquiBand™ wound closure products for use in cranio-maxillofacial (CMF) surgical procedures.

Stryker is one of the largest players in the $35.6 billion worldwide orthopaedic market with products sold in more than 120 countries. The CMF segment represents $900m of this market with

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Stryker being globally recognised as the leader in this specialty field which involves surgical procedures resulting from fracture repair and deformity correction in the head and neck.

Under the terms of the agreement, Stryker will have exclusive marketing and distribution rights for predominantly all geographical markets for CMF, with product launches to the European market, where the products are approved, commencing in August 2009 and a phased roll out in the rest of the world following thereafter. Sales by Stryker into the US CMF market are expected to commence later this year following FDA approval of the relevant products.

LiquiBand™ is a range of topical tissue adhesives based on cyanoacrylate adhesive technology developed for medical applications covering the whole spectrum of wound closure in the Emergency Room (ER) and Operating Room (OR). Tissue adhesives offer significant benefits over conventional ways of closing wounds following trauma or surgical incisions. They are simple to use, non-invasive, help to reduce the risk of infection, minimise trauma to the patient and provide good clinical and cosmetic outcomes.

Commenting on this agreement, Dr. Don Evans, Chief Executive Officer of Advanced Medical Solutions, stated:

"Given the broad application for the current and future LiquiBand™ product portfolio, we believe that the optimal commercialisation strategy is via multiple partners with specific competencies and experience. I am therefore, delighted that we have been able to sign Stryker as our first global marketing and distribution partner, taking our LiquiBand™ technology into the CMF arena. As a leader in this surgical speciality, they are an ideal partner to create and develop this market for our products."

Covidien Recognized as Top Medical Devices Innovator

Patent Board Ranks Covidien's Patent Portfolio as Strongest in the Industry

From BUSINESS WIRE

Covidien, a leading global provider of healthcare products, was ranked the top innovator in the medical devices and services industry by The Patent Board™, the official patent ratings partner of ***The Wall Street Journal***. The Patent Board Scorecard ranked 122 companies in the industry by patent portfolio strength. The Scorecard is a tool to recognize that patent portfolios are measurable financial assets that can be market-value drivers.

In 2009, Covidien moved up from the number two position to take the #1 spot in rankings for the first time, driven by a 50% increase in Technology Strength™, an overall assessment of a company's intellectual property quality and quantity, and a 27% increase in Industry Impact™, the extent to which others are building on Covidien's portfolio of U.S. patents. Covidien first appeared on the Patent Scorecard in 2007, the year that it became an independent company, and ranked No. 4 on the Scorecard that year.

"Covidien's continued dedication to the innovation process is reflected in our achieving this prestigious number one ranking. It underscores the depth of our intellectual capital and our collaborative approach to intellectual property development," said Joe Almeida, President, Medical Devices, Covidien.

Covidien led the industry in Technology Strength—a key indicator that is the basis of The Patent Board's Patent Scorecard rankings. Covidien also showed significant gains in other ranking measures, including Industry Impact and Science Strength™. The Science Strength indicator shows a company's overall reliance on scientific research in its patenting activity.

"Covidien's performance was exceptional. The company demonstrated a substantial advance in Science Strength, increasing its score by 80 percent since the previous Patent Scorecard," said Christine Wren, Director of External Communications, The Patent Board.

Covidien has a strong science-linked patent presence in all four of its segments – Medical Devices, Imaging Solutions, Pharmaceutical Products and Medical Supplies – and will continue to strengthen its technology development efforts. Covidien's businesses work together to turn Covidien's technology advances into patents and other valuable IP assets for the Company.

Anti-Infection Continued from Page 3

The coating is measured on the nano scale; one nanometer is one billionth of a meter.

"Interleukin-12 will maximize the body's natural response to an extent where infections can be prevented without the risk of the offending bacteria developing resistance to the treatment, as is becoming more of a problem with antibiotic therapy alone. With nanocoating, the drug is right where it needs to be—at the interface of the implant and your tissue," Li said. "With the microcapsule, the drug can be injected or sprayed where desired, and the nanocoating and microcapsule prolong the half-life of interleukin-12."

In both methods, because the interleukin-12 is delivered locally rather than spread throughout the body, as in antibiotic therapy, side effects are minimal, Li explained.

Li drew his team from the WVU Department of Orthopaedics, the WVU School of Pharmacy, the National Institute for Occupational Health and Safety (NIOSH), and the WVU Department of Microbiology, Immunology and Cell Biology.

Li, who is also a guest researcher with NIOSH, is giving a presentation on the technology later this summer to officials from the Naval Medical Research Center in Silver Spring, Maryland. He is also working with Christopher Kolanko, Ph.D., a Department of Defense consultant for the WVU Research Corporation, and program managers with the Department of Defense, to discuss further research possibilities and possible military applications.

Li's team has spent the past four years developing the technology, funded in part by the WVU Research Corporation, the National Science Foundation and the Osteosynthesis and Trauma Care Foundation.

Meeting/Conference/Trade Show Calendar

Meeting/Conference/Trade Show	Dates	Place	Web Address
International Conference of the IEEE Engineering in Medicine and Biology Society	Sept 2-6	Minneapolis, MN	embc09.org/
22nd European Conference on Biomaterials	Sept 7-11	Lausanne, Switzerland	esb2009.org
MEDTEC China	Sept 8-10	Shanghai, China	devicelink.com/expo/shanghai08/
BioPharm America 2009	Sept 16-18	San Francisco, CA	baybio.org/wt/page/BioPharm_America
Transcatheter Cardiovascular Therapeutics (TCT)	Sept 21-26	San Francisco, CA	tctmd.com
GeneAcres17	Sept 30	San Francisco, CA	baybio.org/wt/home/GeneAcres17
Orthopedic Design & Technology (2nd annual)	Oct 6-8	Fort Wayne, IN	odtexpo.com/
American Neurological Assoc (ANA)	Oct 11-14	Baltimore, MD	aneuroa.org/index.php?src=gendocs&ref=2008SLC__Home
VIVA (Vascular Interventional Advances)	Oct 19-23	Las Vegas, NV	vivapvd.com/index.cfm
Medical Device & Manufacturing Minneapolis	Oct 21-22	Minneapolis, MN	devicelink.com/expo/minn08/
International Conference on Surface Metrology	Oct 26-28	Worcester, MA	surfacemetrology.org
BioInterface 2009	**Oct 26-28**	**San Mateo, CA**	**surfaces.org**
American Association of Pharmaceutical Scientists (AAPS)	Nov 8-12	Los Angeles, CA	aapspharmaceutica.com/meetings/futuremeetings/index.asp
American Heart Association (AHA)	Nov 14-18	Orlando, FL	scientificsessions.americanheart.org/portal/scientificsessions/ss/seeyounextyear2009
Medica	Nov 18-21	Dusseldorf, Germany	medica.de
BIOMEDevice 2009	Dec 9-10	San Jose, CA	devicelink.com/expo/biomed08/

Save the Date!

BioInterface 2009

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October 26-28, 2009

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- Student Town Hall Meeting: The place where students can "meet the industry" during a luncheon. This Q&A plus networking session is a successful introduction for students to industry perspectives.
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- Lively debate session
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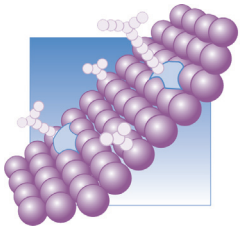

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