Medical Device Daily™
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International Stroke Conference

CAE vs. CAS heatedly debated at ISC session

By LARRY HAIMOVITCH
***Medical Device Daily* Contributing Writer**

LOS ANGELES — The purpose of a clinical trial, particularly a huge, multi-center, prospective and randomized one, is to provide sufficient data to guide physicians to deliver the best care for their patients. The vast majority of trials, whether device or drug-based, generally achieve this goal.

However, based on the heated debate about how to treat carotid artery stenosis that occurred at this year's **International Stroke Conference**, which is sponsored by the **American Heart Association** (AHA; Dallas), that clearly does not appear to be the case.

Recall that the 2010 conference featured the release of data from the landmark and keenly anticipated Carotid Revascularization Endarterectomy versus Stenting Trial

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NovaVision hopes to bring VRT technology to forefront

By OMAR FORD
***Medical Device Daily* Staff Writer**

Every year millions of people suffer from neurological vision loss due to brain or optic nerve injuries like stroke, tumors, or trauma – unaware that there could possibly be a treatment that would help them regain their sight. This partial blindness can often times be reversed thanks in part to a treatment procedure that **NovaVision** (Boca Raton, Florida) has developed.

The company, which was recently acquired by **Vycor** (Bohemia, New York), is hoping to get a wider adoption of its non-invasive visual stimulation-based Vision Restoration Therapy (VRT) technology, after previous unsuccessful attempts to penetrate the market.

"This is a therapy for patients with stroke or trauma to the brain," Tom Bridges VP of Marketing for NovaVision told

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International report

InspireMD reports deployment of first MGuard in South Africa

A *Medical Device Daily* Staff Report

InspireMD (Tel Aviv, Israel), developer of the MGuard net protective stent system, and **Tau Medical** (Johannesburg) InspireMD's exclusive South African distributor, reported that MGuard is now available in South Africa.

Graham Cassel, MD, performed the first deployment of the MGuard, mesh-based coronary stent system at **Netcare Milpark Hospital**. Cassel is president of the **South African Society of Cardiovascular Intervention** (SASCI; Tygerberg). The patient had suffered a heart attack and the PCI procedure was completed with optimal results and absence of any complications, according to the company.

"I had high hopes for this innovative system and my initial experience with MGuard was superb," Cassel said.

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Washington roundup

Congress late to patent reform, but PTO funding still a problem

By MARK McCARTY
***Medical Device Daily* Washington Editor**

WASHINGTON — Thanks at least in part to the persistently laggardly economy, patent reform is back in vogue on Capitol Hill as the Feb. 11 hearing in a House Judiciary subcommittee indicates. The committee's members uniformly signaled a big interest in passing patent reform legislation this year but as inventors know, the courts and the U.S. Patent and Trademark Office have addressed many of the issues that were afoot when this latest effort commenced in 2005.

The problem this time around may be that a recently passed Senate bill holds on to features that some observers see as obsolete thanks to the courts and

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Don't miss today's MDD Extra: Neurology

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AHC Media

Court report

Court enters final judgement in LightLab Imaging case

A *Medical Device Daily* Staff Report

The Superior Court of Massachusetts reported that it entered a final judgment incorporating the court's earlier rulings rejecting the claims of **LightLab Imaging** (Westford, Massachusetts) that either **Volcano** (San Diego) or its wholly owned subsidiary **Axsun Technologies** (Billerica, Massachusetts) used LightLab trade secret information in the development of the Volcano Optical Coherence Tomography System or the Axsun OCT laser.

LightLab is an indirect wholly-owned subsidiary of **St. Jude Medical** (St. Paul, Minnesota).

The statutory violations arose in connection with Volcano's acquisition of Axsun Technologies, a key LightLab supplier, in 2008.

"After two-plus years of litigation, we are gratified by the court's decision. Neither Volcano nor Axsun used any of LightLab's purported trade secrets in Volcano's development of its OCT System, or Axsun's OCT tunable laser," said Scott Huennekens, president/CEO of Volcano. "With LightLab's trade secret allegations now behind us, we will continue to focus our energy on developing key products that improve patient care," said Huennekens.

The final judgment awarded damages to LightLab of only $600,000, although LightLab initially claimed damages of more than $200 million. In addition, the final Judgment reimbursed LightLab mandatory attorneys' fees and costs in the amount of $4.5 million, although LightLab requested $8.9 million.

The final judgment rejected the vast majority of LightLab's trade secret claims. The court reiterated its previous findings that only three items were trade secrets misappropriated by Volcano and Axsun, none of which are

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MDD Fun Facts

Forget the flowers and candy, and you may experience these symptoms!

In the Victorian era, female hysteria was a sexist catch-all diagnosis for women in distress, and a goldmine for doctors who were either too credulous to do due diligence or too licentious to pass up an unrestricted sex act certification. The symptoms were ambiguous (discontentment, emotional outbursts, weakness, nerves) and its history was sexist (Plato blamed the wanderings of an "unfruitful" uterus).

The treatment for hysteria was "hysterical paroxysm" (now called "orgasm"), which was administered by physicians either manually or with a vibrator. Traveling doctors would make numerous daily house calls, while husbands (most of whom had no idea women could have orgasms too) naively waited in the next room. Behind closed doors and under a veil of doctor/patient confidentiality, there is no record of these treatments.

Another therapy involved prescribing "hysterical" women to bed rest with orders to refrain from working or socializing, a misguided treatment that usually exacerbated anxiety or depression.

Hysteria petered out during the 20th century, in favor of contemporary diagnoses such as conversion and dissociative disorders, while the physician's role of actual therapeutic application has been assumed by willing pool boys, gigolos and "he's just a friend"-types.

– Michael J. Harris, Fun Facts Editor

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HIT roundup

Optasia Medical wins 510(k) clearance for SpineAnalyzer

A *Medical Device Daily* Staff Report

Optasia Medical (Manchester and Sudbury, Massachusetts) said it has received 510(k) clearance from the FDA for SpineAnalyzer, a workflow tool for the quantitative assessment of vertebral deformaties in patients at risk of osteoporosis.

The output of the device may be used by physicians to assist in the diagnosis of vertebral fractures, a key factor to determine if therapeutic intervention is indicated, the company said. Optasia has recently established distribution capability in the U.S. and plans a formal launch of SpineAnalyzer.

"The aging population and resulting increase in the number of patients suffering from osteoporosis is placing an ever increasing burden on healthcare systems, yet the existing tools to assist with the diagnosis of vertebral fractures are inadequate," said CEO Peter Steiger. "In 2005, over 2 million osteoporosis-related fractures occurred in the U.S., a number expected to reach 3 million by 2025. The costs related to these fractures were $16.9 billion in 2005 and are predicted to rise to $25 billion by 2025. Despite the availability of bone densitometry and pharmacological therapies, the incidence and costs related to osteoporosis have not decreased."

Optasia makes software designed to facilitate the reading of X-rays for the management of musculoskeletal diseases.

In other HIT news:

• **McKesson** (Atlanta) said it has received complete HER certification for its Horizon Ambulatory Care outpatient electronic health record. The certification means the software is capable of enabling providers to meet the Stage I meaningful use measures required to qualify for funding under the American Recovery and Reinvestment Act.

• **GE Healthcare** (Barrington, Illinois) and **Butler Health System** (BHS; Butler, Pennsylvania) reported the planned implementation of a health information exchange to enable clinical information access between BHS and its affiliated and independent physicians, as well as referral hospitals outside the community.

"We've partnered with GE to create an extensible health information exchange (HIE) that we will use to better communicate and coordinate care with physicians across our community," said Chuck Oleson, chief information officer of BHS.

Butler's HIE will provide data to GE Healthcare's ambulatory electronic medical record – Centricity EMR – as well as non-GE clinical software products. GE will integrate HIE data seamlessly with these existing systems, enabling physicians to view newly-available clinical patient information from various sources within their native EMR screens, thereby potentially increasing physician adoption of the HIE by eliminating the need for new sign-on credentials and new screens to learn.

In addition, BHS said it is recommending software-as-a-service based ambulatory EMR's, such as GE Centricity Advance, to help drive EMR adoption by small independent physician practices in the surrounding communities.

• **Clinic Service Corporation** (Denver), a medical billing and practice management firm, said its C-Suite electronic medical record solution received meaningful use certification.

• **Mobily** (Riyadh, Saudi Arabia) and **Great Connection** (San Diego), creator of Mobile Baby service, reported the launch of the first mobile medical imaging service that enables ultrasound stills, 3-D images and video clips to be sent directly from an ultrasound machine to a mobile device. Mobile Baby is a new service offered to Mobily network subscribers, as well as a pioneering initiative to enhance pre-natal healthcare through immediate availability and low-cost transmission of high-quality images and video clips from the womb.

Mobily is the first mobile operator to make the Mobile Baby mobile health service available to subscribers. The application is compatible with any ultrasound machine and enables high-quality, 2-D and 3-D images and video to be delivered to any mobile device via MMS and email. ■

Restructuring roundup

Cordis to make cuts, merge two vascular sales forces

A *Medical Device Daily* Staff Report

Johnson & Johnson (New Burnswick, New Jersey) said its **Cordis** (Miami Lakes, Florida) unit will lay off an unspecified number of salespeople and merge two separate sales forces within the division, according to various media reports.

Cordis' sales have dropped significantly in recent years due to waning demand for its Cypher heart stent. Sales within the Cordis unit fell almost 10% in the fourth quarter, to $629 million.

According to a *Wall Street Journal* report, Cordis is consolidating its cardiovascular and endovascular sales forces into a unified "vascular" sales force.

In other restructuring activity, **C. R. Bard** (Queensbury, New York) plans to cut about 200 positions at the Bay Road plant as it shifts production work to other facilities. The reduction represents about 20% of the plant's 960 employees. About 60 of those jobs are temporary positions, which will be targeted first.

The downsizing will be an ongoing process as the company seeks to "improve its overall cost structure and enhance operational efficiency," C. R. Bard said. ■

Financings roundup

Kips Bay prices IPO to fund vein technology

A *Medical Device Daily* Staff Report

Kips Bay Medical (Minneapolis) reported the pricing of the company's initial public offering of 2,062,500 shares of its common stock at a price of $8 per share. The shares will begin trading on the Nasdaq Global Market under the ticker symbol KIPS. The closing of the offering is scheduled to take place on Feb. 16. The company has granted the underwriters a 45-day option to purchase up to an additional 309,375 shares of common stock at the initial public offering price to cover any over-allotments.

The company said it intends to use the proceeds of the offering to fund the process of seeking regulatory approval to market its external saphenous vein support technology, or eSVS MESH, in the U.S., to fund the development and testing of additional applications of its eSVS MESH, to fund certain milestone payments related to acquired intellectual property, and the remainder, if any, for working capital and general corporate purposes.

Rodman & Renshaw is acting as sole book-running manager of the offering and Newbridge Securities, Caris & Co. and Chardan Capital Markets are acting as co-managers.

Kips Bay Medical is a development stage device company focused on making its eSVS MESH for use in coronary artery bypass grafting surgery. ■

Med-Tech Notes

ArthroCare settles SEC investigation

ArthroCare (Austin, Texas) has entered into a settlement with the Securities and Exchange Commission that fully resolves the SEC investigation against the company that was first reported in 2008 (*Medical Device Daily*, July 25, 2008). The investigation centered around the company's restatement of financial results. Under the settlement, the company has consented to the entry of an administrative order, released today by the SEC, that directs the company to cease and desist from committing or causing violations of the reporting, books and records and internal control provisions of the federal securities laws in Sections 13(a), 13(b)(2)(A) and 13(b)(2)(B) of the Securities Exchange Act of 1934 and under Rules 12b-20, 13a-1 and 13a-13 promulgated under the Exchange Act. The company consented to the entry of the order without admitting or denying the order's assertions of factual findings. No monetary penalty or fine will be imposed on the company, and none of the company's current officers or employees were charged. In accepting the settlement, the SEC specifically considered the company's remedial actions and the substantial cooperation it provided in connection with the SEC investigation.

ArthroCare makes minimally invasive surgical products. Many of ArthroCare's products are based on its Coblation technology, which uses low-temperature radio frequency energy to gdissolve rather than burn soft tissue – minimizing damage to healthy tissue.

Pedicle screw market in contraction

According to **Millennium Research Group** (MRG; Toronto), a specialist on medical technology market intelligence, the market for pedicle screw-based dynamic stabilization systems, already under pressure from the lack of FDA approval for nonfusion indications and 522 postmarket data requirements, will undergo a more significant contraction through 2015 due to the failure of **Applied Spine Technologies** (AST; Rocky Hill, Connecticut) to move forward with its anticipated spinal nonfusion product, Stabilimax.

As of 2010, such pedicle screw-based dynamic stabilization systems were only FDA approved to be implanted immediately adjacent to a surgically fused level of the spine. However, most surgeons used such systems off-label, either as the sole spinal stabilizer, or at levels above and below spinal fusion, a procedure known as "topping off." The expense and difficulty of complying with the FDA's recent request for post-market clinical data demonstrating efficacy and safety was already causing manufacturers to reevaluate the viability of this product line in their portfolios.

As of May 2010, AST had been the only company undergoing an investigational device exemption (IDE) trial for their spinal nonfusion application, Stabilimax. This positioned it to be the first company to enter the U.S. market. In September 2010, however, it reported that it would be attempting to sell its assets, and also terminated its Stabilimax clinical trials. As of the end of 2010 it had not yet succeeded in finding a buyer for its assets.

MedSynergies moves HQ to Irving

MedSynergies (Irving, Texas), a maker of hospital-physician alignment solutions, has moved its headquarters to Irving, Texas, to triple its office space and allow for continued company growth. The new headquarters will combine employees from its previous headquarters at 1255 Corporate Drive in Irving and Three Galleria Tower location in Dallas.

More than 240 MedSynergies employees now occupy 77,000 square-feet on the second and third floors of Two MacArthur Ridge in Irving. As part of its 11-year lease, the office space includes a large break room with seating for more than 70 employees, Internet café, lounge seating, designated "phone rooms" for employees to make private calls and coffee bars throughout.

MedSynergies partners with healthcare organizations and physicians to align their operations.

Stroke

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(CREST). Sponsored by the **National Institutes of Health** (Bethesda, Maryland), CREST enrolled more than 2,500 patients at 117 centers in the U.S. and Canada and took a remarkable nine years to complete.

Patients were randomized 1:1 to either carotid stenting (CAS) or carotid endarterectomy (CEA), with just over half the patients with symptomatic disease. The primary endpoint was a composite of any stroke, myocardial infarction (MI) or death within 30 days. The secondary endpoints contrast CEA and CAS by symptomatic events, sex, restenosis and health-related quality of life (QOL) and cost.

The conclusion from last year's conference was essentially that either procedure is a good way to treat carotid artery occlusions and thus to limit the risks of having a stroke. The choice between the two procedures could be more a matter of patient preference than scientific certainty.

Stated differently, Wayne Clark, MD, a vascular neurologist from **Oregon Health Sciences University Medical Group** (Portland) said, "I am excited to say that we now have two very good options to prevent stroke."

Further, the lead CREST investigator Thomas Brott, MD of the **Mayo Clinic** (Jacksonville, Florida) indicated last year that while the stroke and heart attack rates were different "unfortunately, there is not a lot of scientifically valid information that tells us which is more important to the patient."

A recent guideline document, titled "Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease" was published in the January 2011 issue of *Circulation.* Developed with experts from the AHA and the **American College of Cardiology** (Washington) and several other medical societies, it essentially echoes these viewpoints.

The October 2010 issue of *Endovascular Today* was heavily devoted to this topic, with an editorial from the chief medical editor's page titled "The CAS Data Puzzle." The issue contained numerous articles on the topic from some of the world's most renown experts from vascular and cardiovascular surgery to interventional neurologists, cardiologists and neuroradiologists.

Clearly, CREST is a highly important study and the massive interest in this subject was exemplified here at a session on Thursday morning, with a standing room only crowd to attend talks on "Carotid Angioplasty and Stenting versus Endarterectomy." From the size of the audience to the passionate views from speakers and the audience in a lively Q&A, it was clear that the controversy is still very much alive and indeed, far from being resolved.

The session's moderator Seemani Chaturvedi, MD, professor of neurology at the **Wayne State School of Medicine** (Detroit), kicked off the proceedings, saying that it is especially timely, a year after CREST was unveiled, to re-visit the data and update the medical community. He further noted that recent regulatory developments made it even more important to review treatment options.

Chaturvedi's reference to new regulatory events concerned an FDA Circulatory Systems Devices Panel advisory committee meeting that took place on January 26. The committee considered the application from **Abbott Vascular** (Abbott Park, Illinois) to broaden the indication for its RX Acculink carotid artery stent and companion embolic protection device, the RX Accunet, from patients who are at high risk for a carotid artery endarterectomy procedure to those who are at standard risk (*Medical Device Daily*, Jan. 28, 2011).

With a 7-3 affirmative, the panel basically supported the CREST data and voted to expand the label for this patient population. Final FDA approval is presumably going to follow in the next few months, although the FDA is certainly not obligated to follow the committee's recommendations.

The session here began with Jorg, Ederle, MD, from the **Stroke Research Group, Institute of Neurology** (London), who provided a detailed review of the various trials that have been conducted around the world in the past several years. His two main conclusions were that CAS is riskier than CEA (due to a higher stroke rate) especially in asymptomatic patients and that the efficacy of the two approaches is quite similar, particularly a few years after the procedure has been performed.

Robert Harbaugh, MD, chairman of the department of neurology at **Penn State Hershey Medical Center** (Hershey, Pennsylvania)**,** provided an extensive analysis of the CREST data, noting that the results were quite similar. He was adamant in his opinion that "symptomatic patients are the most important to treat" and later in his remarks, slammed CAS, saying "it is criminal to treat these asymptomatic patients with stenting and angioplasty."

Adnan Siddiqui, MD, assistant professor of neurosurgery and radiology at **State University of New York** (Buffalo, New York), was the final speaker of the session. He took a more balanced approach in his prepared remarks, commenting that "equipoise has been reached" and that "both approaches are very complementary." He noted that the rate of adverse events in carotid stenting has significantly declined with the addition of distal protection devices. This benefit was first demonstrated in the SAPPHIRE trial in 2005 and has continued to be a boon to CAS procedures, according to Siddiqui.

A lively question and answer period brought emotions to a head with Harbaugh and Siddiqui strongly disagreeing on the role of CAS vs. CEA. Harbaugh again reiterated the "criminal" word in regard to Medicare patients being "over-stented," adding that "if we perform stenting procedures on asymptomatic patients, we will cause more strokes than we will prevent."

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NovaVision

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Medical Device Daily. "[The trauma] can be so severe that a patient could lose the left half of your vision. Some of these patients don't even know if they've lost their visual field. They don't realize because they have so much other trauma that has occurred. The type of treatment helps re-establish those pathways for brain and the eye."

According to Bridges, the treatment is performed at home on a leased, computerized device, twice daily for six months. During each session, patients focus on a central point displayed on the device's screen and respond every time they see light stimuli appear. The light stimuli are presented primarily in the areas at the border of the patient's specific vision loss, and become detected more easily and deeper into the area of loss as therapy progresses and the visual field is expanded. Therapy is regularly updated and monitored with input from the patient's prescribing physician. Patients are advised to take breaks during therapy and to take one day off from the therapy per week.

"After six months we're able to recover a very significant part of the patient's vision," Bridges told *MDD*. "There have been some occasions where we have had patients that have gone on with treatment beyond 12 or 15 months - because they say that they keep seeing improvements."

Bridges added that on average patients can permanently recover around 5 degrees of central vision and, in some cases, dramatically more, which is a critical gain for conducting many daily activities.

"While 5 degrees may sound like a small difference, clinical data shows it can have an exceptional impact on patient's lives whether it be through decreased risk of collisions or falls - a well documented problem in those with vision loss, to reading, watching TV, grooming, hobbies and sports, and, in those cases with greater visual recovery, the ability to drive again," he said. "Perhaps most important is the fact that so many of our patients report they gained their self esteem and independence back to a much higher degree."

The company attributes the success of VRT to neuroplasticity, which is the ability of the nervous system to modify its structural and functional organization and reorganize in order to compensate for injury. NovaVision's VRT device uses the eyes as conduit to deliver light-based stimuli to the brain to trigger and accelerate neuroplasticity. The VRT diagnostic program maps areas where vision may be improved, while proprietary algorithms generate a customized neurostimulation strategy specific to each patient that activates the appropriate region within the brain's vision-processing areas. VRT "rewires" the brain's visual system and expands the visual field of the patient to a more normal level, permanently restoring a measure of lost vision.

For nearly eight years the company has had FDA approval for the VRT, but attempts to penetrate the market in the past haven't been met with much success.

"The original company tried various attempts to get into the market," Bridges said. "But ultimately heavy spending, a great deal of debt and an inaccessible product led the company to close its doors and sell its assets off to Vycor."

The company went bankrupt in April of last year.

Last month, Vycor reported it has completed its $900,000 purchase of bankrupt NovaVision - and gave the company a new lease on life and a chance to correct past mistakes.

One of those mistakes was inadvertently limiting the access of VRT and pushing up the costs of the technology to offset debt the company had incurred.

"The company had the VRT technology in 40 centers across the country," he said. "But there were a lot of patients who couldn't make the trips to reach these centers. And because the company was in so much debt, they charged an incredible amount of money for the therapy."

Bridges said that now that company has been acquired by Vycor, it is in a position to start getting the word out about VRT. He added that the treatment procedure is truly different from a lot of products out on the market today.

"Unlike other therapies that help patients simply compensate for, or adjust to, their vision loss, VRT can actually permanently restore visual function and, thus, has a more significant impact on a patient's emotional and physical well-being," Bridges said. "While other rehabilitation modalities such as speech, physical and occupational therapy have been established as a standard of care for stroke and traumatic brain injury victims, our innovative Vision Restoration Therapy addresses a previously unmet need for vision recovery," Bridges said. ■

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Court

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relevant to or used in either Volcano's or Axsun's business operations. The judge merely ordered that Volcano could not see or use the following: the specification for the Axsun laser formerly supplied to LightLab; the specification for the Axsun laser currently supplied to LightLab; and one Axsun prototype laser made in 2008. The remaining injunction terms in the final judgment relate to routine document destruction at the conclusion of litigation, and Volcano's voluntary agreement not to merge Axsun into Volcano for a limited period of time.

Earlier this month, St. Jude Medical claimed victory in the case reporting that the rulings found that Volcano and Axsun violated a Massachusetts law against engaging in unfair competition and unfair or deceptive acts or practices, through a pattern of inappropriate conduct directed at key technology used in the company's Optical Coherence Tomography (OCT) product platform (*Medical Device Daily*, Feb. 1, 2011). ■

International

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"The device is easy to maneuver and I was done with the procedure in less than 10 minutes. This method could become a major breakthrough in the standard care of STEMI (heart attack) patients."

Cassel will lead the South African arm of the MGuard MASTER randomized trial (MGUARD for Acute ST Elevation Reperfusion), a multinational randomized controlled trial designed to demonstrate the MGuard stent's superiority over standard care for STEMI (heart attack) patients.

The MASTER randomized trial will enroll 432 patients. The study's primary endpoint is complete ST segment resolution post procedure. Clinical follow-up will continue for one year and other important secondary endpoints will be measured. The trial will be conducted in 10 countries in Europe, South America and South Africa.

"We are very excited about the launch of MGuard in South Africa," said Ofir Paz, CEO of InspireMD. "This is a country with top cardiologists and a great market potential. I am confident that Tau Medical is the right partner for us to optimize MGuard's success in this lucrative market and to further pursue our clinical program to demonstrate MGuard advantage over standard care in STEMI patients. MGuard continues to win supporters around the world, due in large part to its ease of use, unique thrombus management ability, and the optimal results patients have experienced."

According to InspireMD, MGuard presents a novel combination of a coronary stent merged with an embolic protection specifically designed for acute MI patients. The embolic protection is comprised of an ultra-thin polymer mesh sleeve that wraps the stent. The MGuard coronary stent provides permanent embolic protection, without affecting deliverability. MGuard is CE mark approved.

Imaging Diagnostic installs CTLM in Indonesia

Imaging Diagnostic Systems (Fort Lauderdale, Florida) said it has completed installation and training for its CTLM in Jakarta, Indonesia at the **Hang Lekiu Medical Center**.

Hang Lekiu Medical Center provides multi-disciplined medical care in a patient friendly environment. This progressive medical center offers a variety of services through a network of specialists.

"We are thrilled to have the CTLM system in Jakarta, the largest city in Indonesia. The Hang Lekiu Medical Center and the new arrival of the CTLM system has generated tremendous interest in this exciting new breast imaging technology," said CEO Linda Grable.

The CTLM system has received international certifications and licenses from the European CE mark, CMDCAS Canadian Health screening, China SFDA, India, UL, and ISO 13485.

The CTLM system is a breast imaging system that utilizes laser technology and computer algorithms to create 3-D images of the breast. The procedure is non-invasive, painless, and does not expose the patient to ionizing radiation or painful breast compression. CT Laser Mammography (CTLM) is designed to be used in conjunction with mammography. It reveals information about blood distribution in the breast and visualizes the process of angiogenesis; which is a strong indication of tumor growth.

ALQAEM to launch limited release of UFIT

The healthcare division of **ALQAEM International** (Dubai), said it has placed orders for delivery this quarter and will begin a limited release in March to those M.E.N.A. regions that recognize the CE mark for medical device registration. ALQAEM and Biosign jointly announced the very successful public debut of the UFIT heath monitoring system at Arab Health 2011 in Dubai last month.

UFIT TEN-20 is an online medical device for self-monitoring of blood pressure and blood glucose. The device takes the pulse at the wrist through an inflatable cuff and immediately produces pulse trace, blood pressure and blood glucose measurement results. UFIT TEN-20 does not require any type of blood sampling or under-skin implant. All measurements are indirect, noninvasive, and passive and do not produce any hazardous waste. The results are stored on Biosign servers along with the digital test sample. UFIT TEN-20 is approved under ISO 13485 for the non-invasive measurement of blood pressure and blood glucose, and carries the CE mark. ■

Stroke

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All physicians in the session agreed that another study, measuring CEA and CAS against medical management was sorely needed. Chaturvedi noted that medical management has improved significantly in recent years and that many neurologists contend that most patients can be successfully managed medically.

"We desperately need the stroke neurologists to help us decide which therapy is best for each patient," he said.

A final indication of the smoldering nature of this disease, which accounts for an estimated 125,000 to 150,000 procedures per year in the U.S. is that a few days before this meeting, the cerebrovascular section of the **American Association of Neurological Surgeons** (AANS; Rolling Meadows, Illinois) met in Los Angeles. According to a research report written by analyst Josh Jennings of the investment banking firm **Jefferies & Co.** (New York) a lively CREST debate at AANS occurred because "neurosurgeons are at risk of losing carotid endarterectomy procedure volumes."

Jennings went on to opine that "we now believe that carotid artery stenting procedures can increase five-fold on the heels of a positive panel (meeting) for Abbott's Acculink and pending a positive reimbursement decision by CMS and commercial payers over the next four to five years . . ." ■

Washington

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PTO while the House may end up with a bill that omits some of those features. The House Judiciary Committee intellectual property subcommittee's draft is still in the works, but any substantive changes to the template both chambers have relied on up to now – whatever the differences between the two might have been – are likely to complicate efforts to pass a bill. The Senate Judiciary Committee passed its bill toward the end of January (*Medical Device Daily*, Feb. 1, 2011), but that bill, S.23, retains many of the features that witnesses at Friday's hearing cited as having been rendered superfluous via work done by the other two branches of government.

One sticky wicket remains, however, in the eyes of inventors. To a one, the witnesses appearing at Friday's hearing cited fee diversion as a big problem – if not the primary problem – with the patent process in the U.S., a position that found a sympathetic ear among the legislators in attendance.

IP subcommittee chairman Bob Goodlatte (R-Virginia) opened his remarks by contrasting the technology of yesteryear with today's electronic gizmos, and he commented, "as our industries have changed ... our patent laws are beginning to show their age." Goodlatte tipped off stakeholders as to some of the features that might be omitted from his subcommittee's in-process bill by remarking, "we need to take into consideration what our federal government has done," citing instances in which the courts have addressed "willfulness, damages and others." He said the committee sees "a need to factor those" developments into any legislation.

"In the past few years, frivolous lawsuits" against IT firms "have doubled," creating economic drag, Goodlatte said, but he added that Congress "also need[s] to make sure PTO has the resources it needs." Fee diversion at PTO, he indicated, is a sizable problem, and he added that Congress "must address this issue." This notion has not found a home in S. 23, which addresses fees only in terms of PTO's authority to set fee schedules.

Judiciary committee chairman Lamar Smith (R-Texas), was in attendance at the commencement of the hearing, describing the event as "one of the most important subcommittee hearings" this year. He said the purpose of the hearing was "not to recycle and recite each argument made by every stakeholder" in the past, and that all involved "must identify common ground and establish priorities." Hence the hearing will focus on "the do-able, the practical, and ultimately achievable patent reform," Smith said.

"I am absolutely convinced we are going to be able to find common ground" with the Senate bill, Smith promised, adding that he has a bill in the works that he wants "to circulate with the members and stakeholders." That bill, he said, "needs a few more tweaks to inhibit the abuses that gave rise to the project (of reform) in 2005."

The full committee's ranking member, John Conyers (D-Michigan), laid out the case a couple of times for ending fee diversion at PTO. "Somewhere in the appropriations process, the funds" that are collected by PTO "never find their way back" to PTO, something he said the panel should look at. He suggested that the federal budget cuts of $100 billion proposed by the House Appropriations Committee should not dissuade from the effort to allow PTO to keep its fees. "This is giving the PTO the funds they already collected," he said, and the continued diversion of those fees into the general budget "is creating a serious negative impact on the whole concept of patents and trademarks." Conyers asserted that this is "the number one issue this committee . . . can resolve."

David Simon, chief patent counsel for microprocessor titan **Intel** (Santa Clara, California), who spoke on behalf of the **Coalition for Patent Fairness**, summarized the IP dilemma at Intel. "Every 18 months, our state of the art product is obsolete," a function of Moore's law regarding microcircuit miniaturization, a fact of life that forces the firm to "invest billions of dollars" to keep up the pace of iterative innovation. He said his employer is "investing about $5 billion a year in our factories in this country."

Simon made reference to problems in the past with the standards for patent obviousness and willful infringement, but said the courts have addressed these and other issues, although he said false marking persists as a sore on the system. He said he saw several other problems with the patent system in the U.S., but added, "we think the way to deal with this is primarily through the PTO," urging Congress to "get PTO its money."

Noting that PTO's IT infrastructure is short of state of the art, Simon said the agency should have the funds to "modernize the systems." He said the talent base at PTO could use seasoning and additional staffing, but said of the IT base that Congress should "start there."

"It's not that the office doesn't need additional staff," Simon said, but "having inexperienced examiners" clogging up the system with additional poorly examined applications is not a solution.

Simon said "*inter partes* re-exam has worked well for us" and that any concerns could be addressed with work on the personnel situation at PTO. He made the case that a first-inventor-to-file-system should be accompanied by more strict observation of prior user rights, which his testimony states have "long protected our patent system from races to the [Patent and Trademark] Office." He said a dilution of prior user rights in a first-to-file environment would "flood the Office with pointless and quickly (and presumably poorly) written patent applications" intended to secure IP rights. Simon also said he sees no need for legislation on damages.

Also appearing as a witness was Judge Paul Michel, formerly the chief justice at the U.S. Court of Appeals for Federal Circuit, who informed the subcommittee that "the

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People in the News

• **Orthofix International** (Lewisville, Texas) said that Jerry Benjamin, Orthofix board member and former general partner of Advent Venture Partners passed away unexpectedly on Feb. 8 at his home outside of London; he was 70. Benjamin's career began at Monsanto's healthcare and petrochemical businesses, including a period as director of corporate venture capital. He later joined Advent Venture Partners, serving as a general partner until his retirement. Jim Gero, chairman of the board said, "Jerry Benjamin served Orthofix faithfully throughout his tenure as a highly respected director, and contributed greatly to the company's success. He was a friend for close to two decades, and will be dearly missed by all his colleagues on the board." Orthofix International makes minimally invasive surgical and non-surgical products for the spine, orthopedic, and sports medicine market sectors.

Product Briefs

• **Davol** (Warwick, Rhode Island), a subsidiary of C. R. Bard, said that a study published in February's *American Surgeon* showed patients undergoing complex abdominal wall repair with the implantation of the XenMatrix Surgical Graft demonstrated low levels of recurrence and post operative complications an average of two-and-a-half years after abdominal wall reconstruction. The study is a retrospective analysis of 57 consecutive patients who underwent high risk hernia repairs by five different surgeons using the XenMatrix Surgical Graft as an underlay between March 2006 and January 2008. With an average follow up of two-and-a-half years, the data in this peer reviewed clinical study provides the longest existing post operative view of patients following the implantation of a non-cross-linked porcine dermis product in abdominal wall reconstruction.

• **Stryker**'s (Mahwah, New Jersey) Orthopedics Division reported FDA clearance for its MDM X3 Modular Dual Mobility Mobile Bearing Hip System. MDM X3 is an addition to the company's portfolio of next-generation technologies designed to minimize the risks traditionally associated with hip replacement surgery and address a broader patient population, including both primary and revision total hip arthroplasty candidates. MDM X3 is a third-generation dual mobility device that allows surgeons to offer the benefits associated with Stryker's dual mobility technology to a broader patient population, including those who may benefit from advanced fixation. The dual points of articulation in dual mobility constructs help accommodate multi-directional movement, which provides the potential for greater range of motion and reduced wear compared to competitive fixed implant designs, based on laboratory testing, the company said.

• **Wright Medical Group** (Arlington, Tennessee) reported the release of the Evolve Elbow Plating System (EPS). Developed by a team of elbow surgeons, the Evolve EPS is an anatomic plating system designed to treat fractures of the distal humerus and proximal ulna. Composed of polished stainless steel, the system was designed to accurately match the patient anatomy to reduce the need for intra-operative bending while providing a low profile design to minimize post-operative irritation.

Bohuon replaces Illingworth as Smith & Nephew CEO

A *Medical Device Daily* Staff Report

Smith & Nephew (S&N; London), a maker shoulder and knee implants, named Olivier Bohuon as CEO to replace David Illingworth, who has decided to retire after four years in the job. Illingworth will step down at the end of the annual general meeting on April 14; he will stay on as an employee through August to help Bohuon, CEO at Pierre Fabre, with the transition.

S&N is switching CEOs at a time when investors have been speculating the company has attracted takeover interest. The stock has risen 20% since Dec. 1 after news reports that Johnson & Johnson and Biomet had made approaches to S&N.

The company said Jan. 14 it wasn't engaged in any talks that could lead to a takeover.

"I came to a very personal and difficult decision to retire and return to the U.S.," Illingworth said. He and the board have been working on a succession plan for some time, he said.

Bohuon joined Pierre Fabre on Sept. 1. He previously ran the pharmaceutical business of Abbott.

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principal problem . . . can be summarized by excessive delay," noting that not only is patent pendancy a huge problem, but "the reexamination process is also taking years to conclude" as well.

"Trapped in the patent office today are ... assets that will foster economic growth," Michel said, adding "fixing the funding problem is overwhelmingly the greatest need."

Michel did not assert that lack of money was the root of all PTO evils, saying that reform "must contain sufficiently strong safeguards" for post-grant review, but he argued that "the court-related provisions in recent patent reform bills are no longer needed." He advised Congress to act on the "unusual situation" that industry is "eager to pay higher fees." ■

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MDD's Neurology Extra

Additional Developments in One of Med-Tech's Key Sectors

Monday, February 14, 2011

Keeping you up to date on recent developments in neurology

Memory problems may be sign of stroke risk . . . People who have memory problems or other declines in their mental abilities may be at higher risk for stroke, according to a study that will be presented at the **American Academy of Neurology**'s (St. Paul, Minnesota) 63rd Annual Meeting in Honolulu this April. "Finding ways to prevent stroke and identify people at risk for stroke are important public health problems," said study author Abraham Letter of the **University of Alabama at Birmingham**. "This study shows we might get a better idea of who is at high risk of stroke by including a couple simple tests when we are evaluating people who already have some stroke risk." For the study, researchers gave tests to people age 45 and older who had never had a stroke, then contacted them twice a year by phone for up to 4.5 years to determine whether they had suffered a stroke. The average age of the participants was 67. The study was part of a larger study called the REasons for Geographic and Racial Differences in Stroke (REGARDS) study. During the study, 123 participants who had taken the verbal fluency test and 129 participants who had taken the memory test experienced a stroke. Those who scored in the bottom 20% for verbal fluency were 3.6 times more likely to develop a stroke than those who scored in the top 20%. For the memory test, those who scored in the bottom 20% were 3.5 times more likely to have a stroke than those in the top 20%. The difference in stroke incidence rates between those with the bottom and top 20% of scores was 3.3 strokes per thousand person-years. In general, the differences remained after researchers adjusted for age, education, race and where participants lived. At age 50, those who scored in the bottom 20% of the memory test were 9.4 times more likely to later have a stroke than those in the top 20%, but the difference was not as large at older ages.

How the brain knows what the nose smells . . . Mice know fear. And they know to fear the scent of a predator. But how do their brains quickly figure out with a sniff that a cat is nearby? It's a complex process that starts with the scent being picked up by specific receptors in their noses. But until now it wasn't clear exactly how these scent signals proceeded from nose to noggin for neural processing. In a study to be published in *Nature*, **Stanford** (Palo Alto, California) researchers describe a new technique that makes it possible to map long-distance nerve connections in the brain. The scientists used the technique to map for the first time the path that the scent signals take from the olfactory bulb, the part of the brain that first receives signals from odor receptors in the nose, to higher centers of the mouse brain where the processing is done. "No one could trace signals across neural connections to a specific type of neuron at a specific location before," said biology Professor Liqun Luo. This is Luo's first study of the mouse olfactory system, but his lab has spent 10 years studying olfactory pathways in the fruit fly. Because mouse brains are so much larger and more complex that those of flies, Luo and postdoctoral researcher Kazunari Miyamichi had to develop an entirely new experimental technique. These techniques can be used to do more than just study how mice smell. "The tools we've developed can be applied to trace neural connections of any part of the nervous system," Luo said. The tools could be used to understand how mouse brains process information from their other senses, or how the brain controls movement. The tools could also be adapted for use in rats and other mammalian species, he said. To trace the neural pathways, the researchers injected mouse brains with two viruses, one after the other. The researchers first injected a low-grade virus into the higher centers of a mouse brain, where it infected nearby neurons. This first virus left the neurons susceptible to infection by the second virus, which was injected two weeks later. Genes introduced by the first virus allowed the next virus to infect its way from the higher brain to the olfactory bulb, going in the opposite direction of scent signals. By following the backward progress of the second virus, the scientists could identify the neurons in the olfactory bulb where the virus ended up, thanks to the red fluorescence of the second virus. The researchers found that most of the nerve pathways heading to the higher processing centers that direct the mice's innate like or dislike of certain odors, and trigger a response to them, originated from one region – the top part of the olfactory bulb.

Stroke patients make gains with physical therapy . . . One year after having a stroke, 52% of people who participate in either a physical therapy program that includes a walking program using a body-weight supported treadmill or a home-based program focused on progressive strength and balance exercises experience improved functional walking ability, according to the results of the Locomotor Experience Applied Post-stroke (LEAPS) trial being presented Feb. 11 at the **American Stroke Association**'s (Alexandria, Virginia) International Stroke Conference 2011 in Los Angeles, and Feb. 12 at the American Physical Therapy Association's (APTA) 2011 Combined Sections Meeting in New Orleans. The LEAPS trial, led by physical therapist and APTA member Pamela Duncan, PhD, included 408 participants (average age, 62) with recent stroke recruited from 6 U.S. stroke rehabilitation centers between April 2006 and June 2009. Participants were 45% female, 58% Caucasian, 22% African American, and 13% Asian. All were assigned to 36 sessions of 75 to 90 minutes for 12 to 16 weeks in either a structured and progressive task-specific walking program that included body weight supported treadmill training provided early (2 months post-stroke) or late (6 months post-stroke), or a structured and progressive home-based exercise program of strength and balance provided 2 months post-stroke. "The investigators hypothesized that the body-weight supported treadmill and walking program, especially early locomotor training, would be superior to a home exercise program; However at 1 year, the early walking group, late walking group, and exercise program targeting strength and balance achieved similar important gains in walking speed, motor recovery, balance, functional status, and quality of life," said Duncan, professor at **Duke University School of Medicine** (Durham, North Carolina). "Additionally, walkers with severe and moderate limitations improved with all programs. In all groups, the biggest improvements in outcomes were made after the first 12 sessions of therapy, but 13% of the subjects continued to make functional gains in walking recovery by 24 sessions and another 7% improved by 30 to 36 sessions."

Little-understood aging brain disease studied . . . The population of aged persons worldwide is expanding rapidly, and it is becoming increasingly clear that there are many different diseases that affect the minds of these individuals. Researchers at the **University of Kentucky** (Lexington) are breaking new ground in the ongoing project of identifying and defining those diseases most likely to affect an aged population. Peter Nelson of the University of Kentucky Sanders-Brown Center on Aging is the lead author on a paper soon to be published in the journal *BRAIN*; the paper deals with the little-understood but serious condition hippocampal sclerosis (HS-AGING). He is also the recipient of a newly approved grant from the National Institutes of Health (NIH) to conduct a study of HS-AGING genetics. Many different diseases may produce symptoms of dementia – defined as cognitive decline and impaired memory – in aged persons. Although Alzheimer's disease is probably the most recognized cause of dementia, HS-AGING also causes serious cognitive impairment in older adults. In those who live to a very advanced age (beyond the age of 95) HS-AGING is roughly as prevalent as Alzheimer's. It is important for physicians and scientists to understand the unique pathology of HS-AGING, and to be able to differentiate it from other diseases, as it is only by making an accurate diagnosis that clinicians can hope to treat people who present with signs of cognitive decline. Nelson, a neuropathologist, analyzed autopsy data from 1,100 individuals, each with substantial clinical data available from before death. The long-term clinical information was obtained through the University of Kentucky Alzheimer's Disease Center, the Nun Study and the Georgia Centenarian Study. The large numbers of patients and the high quality of the data enabled the research team to gather new clues about the prevalence and impact of HS-AGING. "We and others have shown previously that HS-AGING has a strong impact on cognition. The goal of the new study was to define HS-AGING as a distinct disease entity," said Nelson. "There were some surprises. The high prevalence of HS-AGING in individuals older than 95 was unexpected. In addition, by analyzing neuropathological data alongside clinical data, we were able to determine that there is a recognizable cognitive profile for individuals likely to develop HS-AGING," said Nelson.

– Compiled by Rob Kimball, *MDD* Staff Writer
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