

BUSINESS BRIEFS WEEK IN REVIEW

Bracco and GE execs speak between the lines of a court ruling and its \$11.4 million verdict favoring the Italian maker of contrast media. Will intelligent robots plumb the archives of electronic medical records?.

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By Greg Freiherr

The Chinese market for x-ray equipment will be an oasis in the economic desert, if a new report from InMedica proves correct.

The upbeat analysis predicts rising demand for x-ray equipment in China that will push annual sales to \$873 million by 2012, representing a compound annual growth rate of 9.3% from 2009 forward. InMedica analysts base the forecast on continuing strong economic growth and increased expenditure on public healthcare, coupled with the country's transition from analog to digital x-ray systems. The market research firm notes “tremendous demand for high-end x-ray equipment, especially mobile C-arms and digital radiography.” If the predictions are correct, the Chinese x-ray market could serve as a buffer for the economic turmoil elsewhere in the medical imaging market, as more than 80% of the demand for digital radiography in China is currently met by multinational suppliers. Tertiary hospitals have strict requirements for x-ray equipment, and local manufacturers find it hard to compete, according to InMedica.

GE and Bracco spar over meaning of court ruling

Damages and sales approach for contrast agents hang in balance

Rather than settling the feud between GE and Bracco over the marketing of GE's Visipaque contrast agent, the U.S. District Court for New Jersey ruling in late March may simply have broadened the venue of debate from the courtroom to the public arena.

In the days after the decision, executives at the two companies gave *DI SCAN* markedly different interpretations of the significance of the case and the court's findings.

Bracco execs Carlo Medici and Alberto Spinazzi painted the decision in black and white, noting the court's finding that GE used false advertising to win sales for its x-ray contrast agent Visipaque at the expense of Bracco's Isovue agent. As a result, GE Healthcare is permanently enjoined from making such claims and must pay Bracco damages of \$11.4 million, according to Bracco. GE also must take corrective actions to ensure that healthcare provid-

ers are informed about the court's findings.

GE exec Eric Cantor, however, sketched the ruling in shades of gray, describing GE sales and marketing of Visipaque and all GE products as transparent, ethical, and within established industry and government standards.

“The court found that there were some specific extrapolations that led to false advertising,” said Cantor, head of medical and professional affairs for GE Medical Diagnostics. “But the court in many ways found that the majority of GE Healthcare's messages were in fact true and were properly relied upon and were based on reliable scientific studies to support them.”

Initially, Bracco asked the court for a billion dollars in damages. The award was much less. Medici noted, however, that the \$11.4 million damages were among the most ever awarded by a U.S. court in a case built on allegations of false advertising. Cantor counterpunches that the award was limited by Bracco's failure to prove lost business in line with its billion dollar demand for damages.

In an interview with *DI SCAN*, Cantor discussed the findings of the court in the context



Unveiled by ContextVision last week at the 2009 American Institute of Ultrasound in Medicine meeting, GOPiCE US filters 3D ultrasound data in real-time. The software enhances volumetric images by removing speckle and other artifacts while simultaneously extending the clinician's vision to planes previously hidden. Initial image shows fetal spine and thorax demonstrating campomelic dysplasia (left). Improved contrast and edge enhancement are apparent in GOPiCE image (right).

Long-time partner Virtual Imaging has joined the Canon USA fold. The U.S.-based subsidiary of Canon announced April 2 the purchase of the Deerfield, FL-based distributor of its digital radiography systems. In business since 1995, Virtual Imaging runs a national sales and service organization composed of 100 staff. Clients range from large hospitals to private physician offices.

The merger between Amicas and Emageon is done. Emageon shareholders ensured that their company would become a wholly owned subsidiary of Amicas with the tendering of 18,882,734 shares of the common stock by the deadline of midnight April 1, which sews up 88% of outstanding shares for Amicas. With Amicas' purchase of newly issued shares, that company now holds more than 90% of outstanding Emageon shares, effecting a short-form merger without the need for a meeting of Emageon shareholders. In the merger, the company will acquire all other Emageon shares (other than those to which holders properly exercise dissenters' rights) at the same \$1.82 per share price.

The only commercial provider of an FDA-approved MR vascular agent is teetering on the edge of insolvency. A financial audit of Epix Pharmaceuticals led the company to issue a "going concern" alert on its Form 10-K, filed March 13 with the Securities and Exchange Commission. Despite dedicating more than 10 years to the development of its VasoVist blood pool agent, Epix Pharmaceuticals now is pursuing therapeutic agents, looking to sell off all rights to the MR agent.

Blaming the global economic downturn and a weak U.S. dollar, digital radiography provider Imaging Dynamics reported a 62.8% drop in revenue in the fourth quarter, ended Dec. 31, 2008, compared with the year-earlier quarter. The steep decline in the quarter to revenues of \$3.1 is continuing, according to the company. Revenues are down 48% so far this year compared with the same time last year. Despite the downturn at

of events that spurred Bracco to bring the litigation, instances that occurred in and around 2003. Bracco execs, however, were not so constrained by time in their references.

"For seven years, they made the false claims, and we took a hit in the marketplace; we took a severe hit, and so we felt damaged," said Medici, president and CEO of Bracco Diagnostics.

The Bracco top exec asserted that GE's false ads allegedly "generated hundreds of millions of dollars in profits for them." He noted, however, that Isovue improved its position in the market from 2003 to the present and, thanks to the court ruling, stands to gain even more.

"We now have 34% market share; one third of the procedures in the United States, use our product," Medici said. "Isovue is the number one brand in the United States and so we believe that our strategy in the marketplace has been successful, and now it is going to be confirmed and strengthened by this court's ruling."

Executives at the Italian company are keeping tabs on claims now being made by GE Healthcare, Medici told *DISCAN*, and they don't like what they're seeing. At issue is the way GE uses data obtained from the Nephrotoxic Effects in High-Risk Patients Undergoing Angiography (NEPHRIC) clinical study, published in 2003 by *The New England Journal of Medicine*, that compared the toxicity of two GE agents: Visipaque and Omnipaque.

Bracco claimed—and the U.S. District Court agreed—that GE's extrapolation of results to x-ray agents other than the ones in the NEPHRIC study was invalid. The use of these clinical data, therefore, to argue that Visipaque is less toxic in high-risk patients than competing contrast agents, particularly Bracco's Isovue, constituted false advertising, the court ruled.

"But today we are looking at their website, and we found that the NEPHRIC study is presented the same old way," Medici said.

He acknowledged that GE is not in violation of the court ruling, as the company has 60 days from the date of the judgment to comply. This includes continuing to make claims considered by the court to be false, he said.

Cantor insists that GE will fully comply with the court's judgment. The company will communicate information about Visipaque and competing products that is factual, timely, and

balanced, he said.

"We have processes in place to make sure that the information we communicate is appropriate to the science behind the messages that the court found were in error," Cantor said.

But the message GE plans to send is not all *mea culpa*.

"I wish to make it clear to the public this decision in many ways actually vindicated the policies, procedures, and science behind the work that we do at GE Healthcare," he said.

Cantor pledged to provide scientific information regardless of whether it supports the Visipaque product.

"If there is information that is generated that does not support our brand, we will be transparent about it," he said. "We will continue to work as accurately and methodically and scientifically as we can to obtain that data to invest in the research to support patients and customers."

Cantor is not so certain, however, whether the court judgment that called GE efforts into question will stand. The company's attorneys, he said, are considering an appeal of the verdict. A decision whether to proceed with an appeal will be made in 60 days from the court's decision, according to Cantor.

Google-like technology shines at HIMSS 2009

Softek's Illuminate searches PACS databases to uncover trends

Softek cast its Illuminate product in the direction of Philips Healthcare, hoping to hook visitors earlier this week to Philips' booth at HIMSS 2009.

The company set up across from Philips on the HIMSS exhibit floor for good reason. Philips' iSite PACS runs the plug-and-play data-mining technology, which digs through the data stored on iSite to find information about the performance of imaging equipment, protocols, and staff.

Softek touted the technology as the means for boosting productivity from radiology suites, squeezing more reimbursement from government and third-party payers, and improving the quality of patient care. It does so, according to company CEO Matt McLenon, by analyzing trends, determining the results of exams in the

context of their cost, tracking cases for maximum insurance reimbursement, and comparing reports against quality benchmarks to determine how they stack up.

"Insurers and government agencies are enacting voluntary and mandatory programs for reporting quality," said Dr. Safwan Halabi, senior staff radiologist and director of imaging informatics at Henry Ford Health System in Detroit. "If health systems are unable to retrospectively and prospectively evaluate the content and quality of their reports, they may be penalized with decreased reimbursements."

Earlier this year, the imaging informatics group at Henry Ford used Illuminate to plumb the data banks of its PACS to document the radiation dose given children during CT exams. Using Illuminate, the IT team gathered data useful in gauging the effects of different protocols, identifying how staff could cut dosage to pediatric patients without affecting diagnostic quality. These data, according to Halabi, ultimately will be used to develop formal protocols that will bring Henry Ford into compliance with the Image Gently campaign, now being promoted by the American College of Radiology, Society for Pediatric Radiology, American Society of Radiologic Technologists, and American Association of Physicists in Medicine.

At HIMSS 2009, the company used the experience of early adopters of its technology to drive home the value of Illuminate. These experiences were gained in the context of Philips' iSite, where free-text searches of data stored in radiology reports and associated with images are conducted with Illuminate.

Users type in a word, as they would in a Google search, and the software takes over, looking through PACS files with a crawler algorithm developed by Softek. The algorithm gathers and indexes the texts stored on the PACS that correspond to search terms and lists relevant notations in less than a second.

The results may be used to track trends or examine specific questions, as was the case when Henry Ford IT specialists delved into pediatric radiation dose coming from CT. But Illuminate can also be used to improve communications among collaborating physicians. These may be radiologists consulting on a case, or they may be radiologists consulting with referring physicians. Henry Ford Health System uses Illuminate to attach PACS images to notifications sent about a particular report, for example.

Illuminate can also be used to combine clinical

and administrative communications. The Detroit health system uses the technology to notify referring physicians of critical results and to receive confirmation that radiology reports were received. It has also been adapted to track patients, ensuring that follow-up imaging exams are performed, and to determine whether those exams improved patient care.

"If I can follow up with those patients, I can see if I made the right recommendation for certain patients to have a CT under certain circumstances," Halabi said. "If it turns out the patients didn't need the CT, I'll stop recommending it."

CT rises to challenge of managing polytrauma cases

German study demonstrates improved survival following whole-body imaging

CT has been hammered lately by reports raising concerns about patient radiation dose from its use. These reports have circulated without any counterweight of information on good CT dose, particularly in the emergency room, where this modality over the last few years has pushed radiography aside as the standard for patient assessment.

But the value of whole-body CT in early trauma care is vindicated in *The Lancet*, where research by Dr. Stefan Huber-Wagner and colleagues at Munich University Hospital in Germany has just been published. Results demonstrated that the modality increases the probability of survival in severely injured patients with multiple trauma.

Huber-Wagner, a specialist in the trauma surgery department at the Campus Innenstadt of Ludwig-Maximilians-University, compared the probability of survival in patients with blunt trauma who had whole-body CT during resuscitation with those who did not. Huber-Wagner and colleagues used data recorded in the trauma registry of the German Trauma Society to calculate the probability of survival according to the trauma and injury severity score (TRISS), revised injury severity classification (RISC) score, and standardized mortality ratio (SMR), the ratio of recorded to expected mortality.

TRISS is the most widely used method for measuring expected outcome in trauma patients. But the recently developed RISC score is even more precise than TRISS. The study considered data from 4621 patients treated at various German trauma centers. The patients,

the end of last year, the company managed to boost its cash and cash equivalents to \$1.1 million from \$0.7 million in the previous quarter. The down market in the last quarter of 2008 produced a loss of \$0.08 per share compared with a loss of \$0.10 per share in Q4 2007. For the year, the company reported a loss of \$0.21 per share on revenues of \$16,876,980 as compared with a loss of \$0.24 per share on revenues of \$32,446,401 in 2007.

QUICK HITS:

Newly christened **AccelaRAD** will unveil at HIMSS 2009 a service that allows patients unprecedented control over their medical images. SeeMyRadiology.com will allow patients to create personalized libraries of images in a centralized location. Patients will own their digital medical images, choosing which ones to easily and securely share with whom, particularly physicians. SeeMyRadiology.com can be branded with an imaging site's name to enhance recognition, according to AccelaRad, formerly known as Neurostar, which is framing the application as a major step toward realizing the benefits of comprehensive electronic medical records (EMRs). Developed in collaboration with the Ohio State University Medical Center in Columbus and Piedmont Hospital in Atlanta, SeeMyRadiology.com includes a toolkit enabling seamless standards-based image integration with a full range of PACS, EM, and personal health records systems.

Better cardiac wall motion tracking was a highlight of an enhanced Aplio Artida ultrasound scanner appearing in the **Toshiba America Medical Systems** booth during the American College of Cardiology meeting March 29 to 31. The company also introduced a pediatric package and two probes for the Artida. New software onboard the scanner allows the assessment of 3D volume images in a single cardiac cycle. This eliminates artifacts that can appear when volumes from several cycles are stitched together. Operators have the option to view the entire heart or focused

views of the endocardium or epicardium. The ability to view each of these two parts of the heart can be important, as they move at different speeds.

Toshiba's next generation of advanced image processing software was a highlight for the company at the ACC meeting last week. Released in late 2008 on TAMS' Infinix x-ray product line, Advanced Image Processing promises increased accuracy and improved workflow. Preliminary experience at Dallas-based HeartPlace indicates reduced image lag during fluoroscopy and improved image clarity.

Automation was the theme in **Siemens'** booth at the American Institute of Ultrasound in Medicine meeting, April 2 to 5, where the company showcased exam procedures and protocols designed to boost productivity onboard its Acuson S2000. Siemens is also pointing to automated fusion of ultrasound and CT imaging sets possible with the S2000.

With service assuming increasing importance in the IT industry, **Vital Images** hopes to make hay as the first advanced medical visualization provider to achieve certification for Excellence in Service Operations by the Service & Support Professionals Association. The certification ranks the company's support operations, customer satisfaction, service, sales and marketing, product serviceability, technology infrastructure, and human resource systems in the same league as those of HP, Cisco, and Xerox, which have received similar certifications, according to Vital Images.

Zurich University Hospital and Gottingen University Hospital have joined more than 70 institutions in the use of **Varian Medical's** RapidArc treatment. The Swiss and German hospitals are using the technology to treat complex cancers, including head and neck tumors. RapidArc delivers image-guided intensity-modulated radiation therapy two to eight times faster than conventional IMRT.

73% of whom were men, had a mean age of 42.6 years. Some 32% had been given whole-body CT to assess critical injuries.

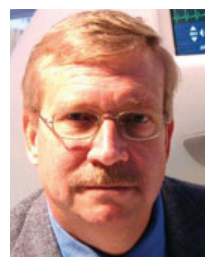
The researchers found that SMR based on TRISS was 0.745 for patients given whole-body CT versus 1.023 for those given non-whole-body CT. SMR based on the RISC score was 0.865 for patients given whole-body CT versus 1.034 for those not assessed with such whole-body scans, indicating that the recorded mortality rate for patients given whole-body CT is significantly lower than that predicted with TRISS and RISC score. The relative risk reduction in mortality for whole-body CT was 25% based on TRISS and 13% based on RISC. Data adjustment confirmed whole-body CT as an independent predictor of survival.

"Integration of whole-body CT into early trauma care significantly increased the probability of survival in patients with polytrauma," the authors report in the article. "On the basis of our findings, we recommend that whole-body CT should be integrated into the early resuscitation phase of severely injured patients as a standard and basic diagnostic method."

In an accompanying comment, Dr. Timothy C. Fabian, a professor and the chair of surgery at the University of Tennessee Health Science Center in Memphis, describes the work as an important contribution to the care of patients with multiple trauma.

"I do not believe that healthcare cost is a substantial concern with whole-body CT," said Fabian, who serves as president of the American Association for the Surgery of Trauma. "Overall, today's study should stimulate the pursuit of further investigations on the usefulness of whole-body CT for trauma assessment."

COMMENTARY



IT robots take a bite from the apple

BY GREG FREIHERR

Automation is the grease that makes workflow glide. Single clicks and macros are lesser elements of this process. The real gains are made under the covers of IT systems by algorithms with a preprogrammed agenda. Far more intelligent tools than these will soon be needed to handle the wave of electronic medical records

gathering off the shores of U.S. healthcare.

No one will be satisfied that EMRs are collecting and dispersing huge quantities of data any more than the mayor of Philadelphia would be happy to see hydrants spewing water at the scene of a fire. All that information collected by the hundreds, if not thousands, of EMR systems due to flood the healthcare system in coming years will have to be channeled to specific purposes, things like assessing reimbursement trends, figuring patient outcomes, and identifying fraud and corruption.

Who in his or her right mind would want to pore over these data to tease out the minutia they contain? How could institutions afford to pay a labor force large enough to crunch those numbers? The answers may lie in a new breed of healthcare IT, one that spins algorithms into artificial intelligence. The first such technology has already arrived: a robot called Adam, a computer system that automates the scientific process.

Created by the Biotechnology and Biological Sciences Research Council, Adam recently became the first machine to independently discover new scientific knowledge. Its creators, scientists at Aberystwyth University in Wales and the University of Cambridge, describe Adam's exploits in a paper published April 3 in the journal *Science*.

Acting autonomously, the robot discovered simple but new knowledge about the genomics of a type of baker's yeast that scientists use to model complex life systems. If done by people, this kind of research is "difficult and irksome," according to Ross King, Ph.D., who led the research at Aberystwyth University, "but [it's] easy for robot scientists."

In its study of baker's yeast, Adam hypothesized that certain genes code for specific enzymes that catalyze biochemical reactions. The robot then devised experiments to test these predictions, ran the experiments using laboratory robotics, interpreted the results, and repeated the cycle.

Encouraged by Adam's success, King envisions teams of human and robot scientists working together in laboratories, their artificial intelligence innovations laying the bricks for a foundation that leads to grander discoveries. Adam's first companion, aptly named Eve, is being designed to help scientists look for new drugs to fight tropical diseases.

Could the offspring of Adam and Eve work on mundane processes that one day transform medical practice in this country? With these two robot scientists already plowing new ground, could finding the answer be as simple as switching orchards?