INTELLECTUAL PROPERTY

Bill Opens Safe Harbor for Research Collaborators

Congress has passed a bill that revises federal patent laws to better protect inventions by collaborators from more than one organization.

The Cooperative Research and Technology Enhancement (CREATE) Act of 2004 (S. 2192) limits the circumstances in which confidential information shared among collaborating partners can prevent the patenting of a team's new inventions. The legislation counteracts a 1997 California federal court ruling that certain information shared among research collaborators with different affiliations could be cited as "prior art" and used to invalidate subsequent applications for joint patents.

Representative F. James Sensenbrenner, Jr. (R-WI) said in a statement to the House, "By enacting S. 2192, Congress will help to foster improved communication among researchers, provide additional certainty and structure for those who engage in collaborative research, reduce patent litigation incentives, and facilitate innovation and investment."

–Kaylynn Chiarello

POLITICS

Capitol Hill Insider to Lead Industry

After months of speculation, the Pharmaceutical Research and Manufacturers of America (PhRMA, Washington, DC, www.phrma.org) announced 15 December that its new president would be William J. "Billy" Tauzin (R-LA), the politically powerful "Cajun ambassador" from Louisiana. Tauzin chaired the House Energy and Commerce Committee until stepping down last February because of criticism about his remaining in a leadership position while negotiating for a high-paying (estimated $2- million salary) job with PhRMA. Critics charged that it was unseemly for a lead author of the 2003 Medicare Modernization Act to be discussing a job at an industry directly affected by his Committee's work.

The Tauzin talks were put on hold when the congressman was diagnosed with and underwent treatment for intestinal cancer. In announcing his new job, Tauzin said that his fight against cancer increases his appreciation of the value of medicines—a theme that will be repeated often as he works to enhance industry's image as a producer of life-saving treatments, as opposed to high-cost, unsafe products.

Tauzin took the reins from Alan Holmer in December and will be bringing in some of his Capitol Hill staffers and other new faces to fill key slots in PhRMA's lobbying and communications operations. At the same time, Tauzin's former colleague, James Greenwood (R-PA), will become the head of the Biotechnology Industry Organization (BIO, Washington, DC, www.bio.org). Neither group is permitted to directly lobby members of Congress for a year, but they are not restricted from talking to administration leaders. And, they can direct others in negotiating with Capitol Hill on proposals related to drug importing, generic biologics, liability protections, and all the other hot issues on the table.

–Jill Wechsler

FILTRATION

Selective Membranes Improve Protein Separation

A new filtration system developed by New Jersey Institute of Technology researchers (NJIT, Newark, NJ, www.njit.edu) can separate proteins of nearly identical molecular weight. While typical systems can separate proteins with molecular-weight ratios of 5–6, NJIT's ultrafiltration technology can purify binary mixtures containing proteins with molecular-weight ratios as small as 1.03.

Three regenerated cellulose membranes—all of the same molecular weight cutoff—are stacked one on top of the other without any gaskets or spaces in between. The rejection of one protein increases with each membrane layer, resulting in a completely rejected species. "The third membrane is exposed to the feed solution, and under appropriate conditions, only one pure protein in the permeate stream will come through. The other protein will remain on the feed side," says Kamalesh K. Sirkar, PhD, distinguished professor of chemical engineering and the project's lead researcher.

According to the research team, the multimembrane system is cost-effective because machines can run continuously. "Using several membranes is not going to cause significant cost increases," says Sirkar. Although the system must be operated at a slightly higher pressure than typical filtration methods, additional pumps or housings aren't needed.

At present, Sirkar is studying whether the ultrafiltration technology can separate mixtures containing more than two proteins. The team also is seeking a corporate partner to bring the technology to market.

–Kaylynn Chiarello

POLITICS

Leavitt Selected as HHS Chief

In a surprise move, President George Bush named former Utah governor Michael Leavitt as the next secretary of the Department of Health and Human Services. A close colleague of the president's since their days in the National Governors' Association, Leavitt was named a year ago to head the Environmental Protection Agency (EPA), where the Utahan has been embroiled in contentious clear air issues that have required all his talent as an administrator and consensus-builder.

The White House nominated Leavitt in December, shortly after former Wisconsin governor Tommy Thompson announced that he would leave the HHS top spot by February 4. Thompson's decision sparked expectations that the new secretary would be Mark McClellan, currently administrator of the Centers for Medicare and Medicaid Services (CMS) and formerly US Food and Drug Administration commissioner and member of the White House Council of Economic Advisors. Evidently the administration considered it more important to leave to McClellan the difficult task of implementing the new Medicare prescription drug program and a host of complex changes to Medicare.

Leavitt's ties to supplement makers and the insurance industry will be fodder for critics at his Senate confirmation hearings. The former Utah governor is well-known to the dietary supplement industry, which is pleased to see HHS in the hands of someone sensitive to their regulatory concerns.

Leavitt is well-liked by his fellow governors, and his three terms as governor of Utah testify to his political and administrative skill. He has backed private sector approaches to expanding access to health care and controlling costs and is expected to champion using information technology to address medical research and treatment challenges.

–Jill Wechsler

PACKAGING

Checkpoint Systems Implements RFID Compliance Network

In an effort to provide solution integrators in the pharmaceutical and retail industry with the latest tools to implement radio frequency identification (RFID), Checkpoint Systems, Inc. (Thorofare, NJ, www.checkpointsystems.com), has introduced the EPC Compliance Network, a consortium of solution providers and third-party logistic firms working together to find the best uses for RFID.

This initiative comes on the heels of a November announcement by the US Food and Drug Administration encouraging pharmaceutical distributors to pilot RFID in the warehouse environment.

According to John Thorn, Checkpoint's general manager of supply chain solutions, the compliance network will provide members and their customers with tools and engineering resources necessary to better understand the characteristics of various tags (labels with embedded microchips) and how well specific tags work on various products.

"The pharma space has taken a serious look at item-level tagging with 1356 Mhz high frequency tags rather than the 915 Mhz tags being used in the retail industry," says Kevin Donahue, director of EPC compliance and services at Checkpoint Systems. "With 1356 tags, the read-range is shorter, but you don't run into problems with read-rate interference caused by certain metallic objects and liquids. This is very attractive to the pharma industry for item-level tagging."

Members will be able to consult RFID experts about the tags and scanning equipment available. According to Checkpoint Systems, the organization will also provide technical training, sales, and cooperative marketing tools.

–George Koroneos

BIOTECH PROCESS

Enzymatic Method Developed for Large-Scale Peptide Production

Ajinomoto Company, Inc. (Tokyo, Japan, www.ajinomoto.com) has developed an enzymatic process for the manufacture of peptides that currently are not commercialized because of their high production costs. Conventional methods are complicated to perform, produce a high level of impurities, and create racemic mixes that must be separated and purified.

In the Ajinomoto method, the amino acid is esterified and the ester is enzymatically coupled with another amino acid. The technique not only enables the production of dipeptides and oligopeptides, but also peptides including non-native types of amino acid.

Ajinomoto is planning to launch alanyl-glutamine as its first product in spring 2005. Whereas current methods produce an unstable form of glutamine, the new technique produces a peptide that can remain stable in a solution over time. Ajinomoto anticipates that this could lead to affordable liquid glutamine supplements. The company is developing other products for commercialization, but final decisions about which products will be released have not been made.

–Kaylynn Chiarello

MANUFACTURING

PAT Survey Reflects Optimism, Uncertainty

During the summer, Stelex (Bensalem, PA, consultants to regulated industries) and *Pharmaceutical Technology* posted a brief on-line survey, probing visitors' awareness of and attitudes towards process analytical technology (PAT) and the US Food and Drug Administration's guidance, *PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance*. Sixty-five respondents registered and completed the survey.

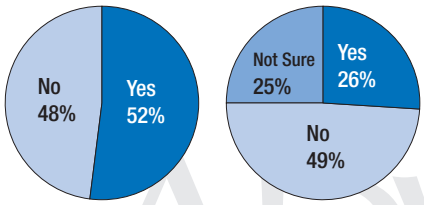
Overall, this small cross-section—self-selected for interest in PAT—claimed only a modest understanding of process analytical technology, its implementation, and its implications. Barely half said their organizations were aware of the PAT guidance, and more than half rated their own PAT understanding as low.

Fourteen percent said that their companies' quality assurance or regulatory affairs departments were currently preparing PAT-based new-product release strategies and SOPs. Just 6% said their companies were preparing PAT-based submissions.

Many answered "not sure" to questions about PAT's ultimate impact, while an even larger group expects PAT—with its improved process understanding and positive feedback controls—to yield improvements in quality, reduce rejects, and even improve usage of capital equipment. The graphs and tables provides a sample of the responses.

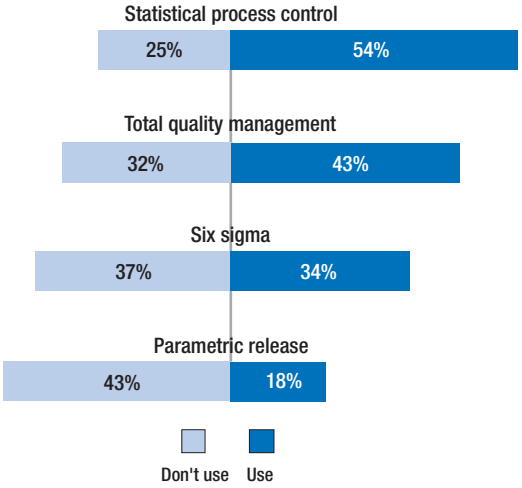
–Douglas McCormick

Does your organization have...

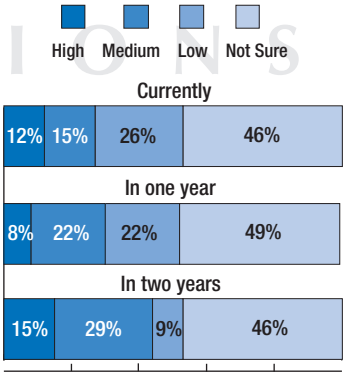


An awareness of FDA's PAT guidance? An established PAT team?

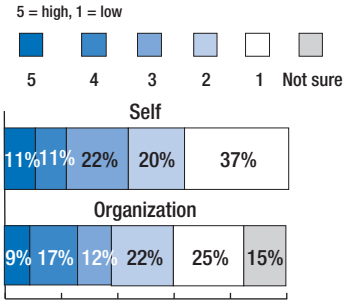
Does your organization already use any of the following engineering tools?



How much of an effect do you see PAT having on your quality assurance and regulatory affairs departments?



How well do you and your organization understand PAT?



Of the following, what do you believe would yield the most valuable data for your PAT program?

Historical incidents	38%
Out-of-specification in-process samples	25%
Product recalls	8%
Equipment downtime	6%
Calibration records	6%
Training records	3%
Regulation changes	2%
Other	12%

Do you agree that the following can be improved through PAT?

	Agree	Disagree	Not sure
Identifying critical sources of variability	65%	0%	35%
Using feedback to control processes and manage variability	63%	2%	35%
Facilitating continuous processing and improving efficiency by reducing downtime	62%	3%	35%
Preventing rejects, scrap, and re-processing	60%	0%	40%
Increasing automation to improve operator safety and reduce human errors	60%	3%	37%