Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

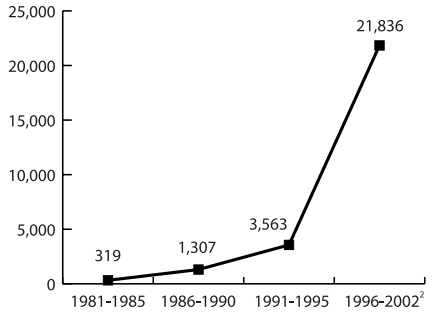
Controversy Grows Over Who Owns Your Genes

Diagnostic testing, biotech and pharmaceutical companies have raced to secure patents on genes in recent years. More than 21,000 gene-related patents were issued between 1996 and August 2002, up sharply from the 3,563 issued between 1991 and 1995, according to a search of the U.S. Patent & Trademark Office database by *Diagnostic Testing & Technology Report (DTTR)*. Fueling the surge are technological advances that have expedited the isolation and elucidation of DNA sequences, such as polymerase chain reaction (PCR) devices and the introduction of automated DNA sequencing devices.

Though the U.S. patent system clearly allows genes to be patented, controversy is growing over the ethical and clinical implications. Earlier this year, legislation was introduced in the U.S. Congress that would greatly weaken the strength of gene patents. And in Europe and Canada, medical institutions and government health ministries are battling to block patents held by Myriad Genetics (Salt Lake City, UT).

For insights into the future of gene patenting, *DTTR* interviewed eight experts in the field. The consensus is that only incremental changes to the patenting system will occur over the next few years, but legal costs associated with defending gene patents may become greater (see *Inside The Diagnostics Industry*, pp. 5-7).

Estimated Gene Patents Issued[1]



[1]Based on the number of patents issued whose claim includes one or more of the following terms: gene, nucleic, polynucleotide, DNA or RNA
[2]Through Aug. 2002
Source: U.S. Patent & Trademark Office

Dade Behring Files For Chapter 11 Restructuring

Dade Behring (Deerfield, IL) has announced that, pursuant to a debt-to-equity swap agreement with its banks and bondholders, it has filed for Chapter 11 bankruptcy protection at the U.S. Bankruptcy Court in the Northern District of Illinois. Under the "pre-packaged" accord, Dade says, its creditors will exchange approximately $700 million of debt for full equity ownership of the company. Current Dade shareholders—which include Bain Capital, Goldman Sachs, Hoechst AG and Baxter International—will be wiped out and required to book investment losses running to hundreds of millions of dollars. *Continued on p. 2*

▲ **Dade Behring Files For Chapter 11,** *from page 1*

Dade says the move, which should be cleared by the bankruptcy court in a matter of weeks, will save more than $50 million in annual interest expense and allow it to begin paying down the principal on approximately $800 million of remaining debt. In addition, according to Dade, the restructuring should enhance customer and supplier confidence in the company's prospects and enable the company to devote more resources to research and development, capital expenditures and other strategic initiatives.

In connection with the restructuring, Dade has arranged a $95 million loan from a syndicate led by Deutsche Bank. The loan is intended to ensure that Dade can meet all ongoing commitments to customers, suppliers and employees without interruption.

Dade says all its current shareholders—except Baxter, which owns less than a 1% stake—are supportive of the restructuring. The bankruptcy court has appointed an examiner at Baxter's request. Dade still anticipates, however, that its plan of reorganization will be approved by the court in a timely manner.

Assuming completion of the restructuring, Dade's banks and bondholders will own 99% of all outstanding equity shares. Dade president and CEO Jim Reid-Anderson and 11 other executives will own the remaining 1%. In addition, Dade says a stock option program could give top management and employees another 15% stake in the company. Dade hopes to have its shares listed on the Nasdaq by late 2002 or early 2003.

The board of the new Dade will have seven members, including six representatives from its banks and bondholders. The seventh seat will be held by Jim Reid-Anderson, the current president and CEO. No decision has been made yet on who will chair the board.

Meanwhile, court documents obtained by *DTTR* show that Dade hit its financial low point in 2000 when it recorded a net loss of $532.7 million (including $149.6 million in interest expense) as revenue slipped 10% to $1.184 billion. Cost-cutting helped the company stem last year's losses to $83.7 million. This year, a loss of $11.7 million is projected. For 2003, a net profit of $30.9 million is projected, assuming completion of the reorganization. Stockholder equity is projected to rise to a total of $636.8 million at year-end 2002 from a deficit of $845.1 million at year-end 2001.

Dade Behring Financials

	Actual			Projected	
	1999	2000	2001	2002	2003
Revenue	$1,318,168	$1,183,695	$1,232,398	$1,195,230	$1,253,744
Cost of goods sold	570,952	583,427	595,618	584,796	603,967
Gross profit	747,216	600,267	636,780	610,434	649,777
Research & development	99,644	103,272	83,663	90,724	104,045
Sales & marketing	237,464	216,398	182,848	182,870	194,098
Interest expense	108,000	149,626	147,261	98,262	66,170
Net income	-38,454	-532,748	-88,674	-11,675	30,871
EBITDA	265,586	195,023	232,219	204,010	232,428
Total assets	1,665,611	1,333,481	1,179,802	1,808,675	1,845,228
Total liabilities	1,808,490	2,035,800	2,024,861	1,171,907	1,174,138
Stockholder equity	-142,879	-702,319	-845,059	636,768	671,090

Source: Dade's filing with U.S. Bankruptcy Court

Inverness To Buy Wampole Labs For $70 Million

Inverness Medical Innovations (Waltham, MA) has agreed to acquire Wampole Laboratories (Princeton, NJ) from MedPointe Inc. (Cranbury, NJ) for $70 million in cash. The acquisition price is approximately eight times Wampole's EBITDA of $9 million and nearly two times its revenue of $40 million for the trailing 12 months. The transaction is expected to close by Sept. 30.

Wampole, which has 75 employees, makes enzyme and fluorescent immunoassay tests to detect infectious and autoimmune diseases, as well as the Clearview product line of rapid tests for determination of pregnancy, group A strep, chlamydia, and C. difficile. The company also is a distributor for a number of small manufacturers of rapid tests.

Inverness Acquisition Summary

Acquisition	*Date*	*Revenue*	*Price*
Unipath	12/01	$87M	$150M
IVC Industries	03/02	70M	27M
Wampole	09/02*	40M	70M

*Expected closing date
Source: *DTTR*

The purchase of Wampole Labs marks the third acquisition by Inverness Medical Innovations since its spin-off from Inverness Medical Technology as part of a November 2001 deal with Johnson & Johnson (New Brunswick, NJ). Since then, Inverness Medical Innovations has acquired the Unipath diagnostics business from Unilever (London, England) as well as vitamin-maker IVC Industries (Freehold, NJ). Including all acquisitions plus its existing business, Inverness Medical Innovations now generates some $250 million in annualized revenue.

Two Consulting Firms To Help Abbott With FDA Consent Decree

Abbott Laboratories (Abbott Park, IL) has hired two third-party consulting companies to help it meet the requirements of its November 1999 consent decree with the U.S. Food & Drug Administration. The newly retained firms—AccuReg (Plantation, FL) and Bio-Reg (Beltsville, MD)—replace Quintiles Consulting (Durham, NC). Abbott fired Quintiles earlier this year after learning that its Lake County diagnostic manufacturing facilities still failed to comply with FDA's quality system regulations (*DTTR, July '02, pp. 1-3*).

In a recent memo, Richard Gonzalez, president of Abbott's medical products group, said AccuReg and Bio-Reg were selected after an extensive search involving more than 20 firms. Both firms will assist Abbott in developing an action plan to build up existing quality systems and identify further enhancements needed to meet FDA's expectations, he noted. AccuReg will assist in implementing the plan; Bio-Reg will monitor progress.

Abbott To Distribute Cholestech's Hemoglobin A1c Test

Cholestech Corp. (Hayward, CA) has signed an agreement with Abbott Laboratories (Abbott Park, IL) for global distribution of its Cholestech GDX System, a CLIA-waived test system for glycated hemoglobin (A1c). A1c testing provides an individual's average glucose level over the previous 90 days and can be used to measure the progress of diabetes therapy management. The American Diabetes Association recommends A1c testing for all diabetes patients up to four times a year.

Bayer To Purchase Visible Genetics For $61.4 Million

Bayer Group (Leverkusen, Germany) has agreed to acquire Visible Genetics (VGI-Toronto, Canada) for $61.4 million in cash. VGI makes the Trugene HIV-1 Genotyping Assay, the only HIV sequencing resistance test approved by the U.S. Food & Drug Administration for marketing in the U.S. VGI also is developing sequencing assays for hepatitis. Sequencing assays are used to assess the genetic make-up of viral specimens. Physicians use the results to better understand a specific patient's resistance profile and adjust drug therapy accordingly.

In the three months ended June 30, 2002, VGI reported a net loss of $11.8 million vs. a net loss of $10.2 million in the same period a year earlier; revenue was up 19% to $4.7 million. VGI has 340 employees worldwide. Its main production facility and U.S. headquarters are in Atlanta, GA.

At the purchase price of $61.4 million, or $1.50 per common share, Bayer is paying roughly three times VGI's annual revenue of approximately $18.6 million (based on annualized second-quarter results). The deal is expected to close in October.

Visible Genetics At A Glance *($000)*

	2Q02	2Q01	% Chg
Revenue	$4,657	$3,928	+19
Cash flow from operations	-5,049	-7,911	NA
Net income	-11,809	-10,197	NA
Cash & securities	31,232	51,022	-39

Source: Visible Genetics

At the height of the U.S. bull market in March 2000, VGI had traded as high as $119 per share for a market capitalization of more than $1 billion. However, market acceptance of the company's Trugene HIV-1 Genotyping Assay, cleared by FDA in September 2001, has been slower than anticipated. The largest U.S. laboratories in particular (Quest Diagnostics and Laboratory Corp. of America) have been reluctant to switch from their "home-brew" genotyping test methods that don't require FDA approval.

VGI charges labs approximately $225 per test kit. Medicare covers HIV-1 genotype analysis under CPT code 87901 at a maximum allowable rate of $355.78 per test. Commercial health plans reimburse HIV-1 genotyping at $350-$550 per test, according to VGI.

Sales At Bayer Diagnostics Up 3% In First-Half 2002

Bayer Group (Leverkusen, Germany) reports that revenue at its Bayer Diagnostics unit (Tarrytown, NY) grew 3% to one billion euros (US $979 million) in the six months ended June 30, 2002. The growth was led, Bayer says, by increased sales of its ADVIA Centaur laboratory analyzer and its Glucometer Elite blood glucose meter. Overall, Bayer Group reported net income of 816 million euros (US $798 million) in the first half of 2002, down from 1.006 billion euros in the same period a year ago; revenue was down 8% to 14.737 billion euros (US $14.4 billion).

Bayer Group At A Glance *(in millions of euros)*

	1st-Half 2002	% Chg
Bayer Group revenue	14,737	-8
Bayer Group net income	816	-19
Healthcare revenue	4,760	-11
❖ Pharmaceuticals	1,900	-24
❖ Biological products	500	+21
❖ Consumer care	900	-10
❖ Diagnostics	1,000	+3
❖ Animal health	400	0
Healthcare operating profit	437	-16

Source: Bayer

Gene Patenting: How Effective Is U.S. Approach? Are Changes Due?

Critics say no one should be allowed to patent a part of human life. Proponents argue that money from gene patents motivates R&D in new diagnostics and drug therapies

Prior to 1980, life forms were considered part of nature and not patentable. That changed in the U.S. when the U.S. Supreme Court ruled, 5-4, in *Diamond vs. Chakrabarty* that genetically engineered (modified) bacteria were patentable because they did not occur naturally in nature. Chakrabarty had modified bacteria to create an oil-dissolving bioengineered microbe.

Since that ruling, patents have been issued on whole genes and fragments whose function is known. The matter appeared to have been put to rest on Jan. 5, 2001, when the U.S. Patent & Trademark Office (PTO) released final patent utility guidelines that allowed a patent as long as credible, specific and substantial utility for a discovered gene or fragment could be demonstrated.

Critics of gene patents say no one should be able to patent human life, and they resent the high prices charged for gene-based tests. Earlier this year, bipartisan legislation (HR 3966, 3967) giving physicians and medical researchers unrestricted access to patented genes for use in clinical testing and non-commercial genetic research was introduced in the U.S. House of Representatives by Reps. Lynn Rivers (D-MI) and Dave Weldon (R-FL). A legislative assistant to Rivers tells *DTTR* that Rivers and Weldon are working to have hearings on the legislation held by both the Judiciary and the Science Committees, but have been unsuccessful so far.

Much of the criticism of gene patenting has fallen on the shoulders of Myriad Genetics (Salt Lake City, UT). Its BRACAnalysis test, introduced in 1996, is covered by nine U.S. patents and is priced at $2,580. BRACAnalysis is a predictive test that analyzes the BRCA1 and BRCA2 genes where mutations indicate a higher risk for developing breast or ovarian cancer.

Timeline For The Gene Patenting Controversy

August 1999	American College of Medical Genetics issues position statement opposing gene patents
June 2000	Human Genome Project and Celera Genomics complete mapping of the human genome
January 2001	U.S. Patent Office issues patent guidelines for genes
March 2002	Reps. Lynn Rivers (D-MI) and Dave Weldon (R-FL) introduce legislation giving physicians, medical researchers unrestricted access to patented genes
September 2001	Paris-based Institut Curie announces plans to fight Myriad Genetics' breast cancer gene patents
September 2001	In Canada, the Ontario provincial government announces it will ignore Myriad's patents and perform its own gene-based tests for breast cancer
August 2002	Switzerland's Social Democratic Party files complaint at European Patent Office over breast cancer gene patents held by Myriad Genetics

Source: *DTTR*

While legislative action in the U.S. appears stalled, some political groups in Canada and Europe are moving aggressively against gene patenting. Most recently, Switzerland's Social Democratic Party filed a complaint at the European Patent Office over Myriad Genetics' breast cancer gene patents. "Genes can't be invented, only discovered," argued Simonetta Sommaruga, a member of parliament. She claims that Myriad is exploiting a monopoly position at a cost to both research and patients. Executives at Myriad did not return calls from *DTTR* seeking comment. We were, however, able to reach executives at eight other organizations linked to genetic testing.

Michael Watson, PhD, executive director of the American College of Medical Genetics (ACMG-Bethesda, MD), notes that many for-profit companies have used government research and financial support as a stepping-stone to gain their gene patents. And now, he says, these companies are seeking to establish high reimbursement from Medicare and Medicaid for their patented tests and therapies. This circle of reliance on government is irrational and leaves the door open for more regulation, he thinks.

Pressure from politicians, physicians and patients may force some lab companies to lower prices on their genetic tests

ACMG has come out in support of the Rivers-Weldon legislation. Watson says restrictions on the availability of gene testing have long-term implications beyond patient care, including limiting the knowledge and training of the next generation of medical and laboratory geneticists, physicians and scientists. He believes some genetic testing companies are charging exorbitant fees for their patented genes and tests in order to subsidize their pharmaceutical development efforts.

Watson is skeptical that any major changes in U.S. gene patenting laws will be enacted. He is, however, hopeful that the PTO will become more stringent in the requirements that companies must meet to show the utility of a gene discovery before a patent is issued.

Tony Shuber, chief technology officer at Exact Sciences (Maynard, MA), is in favor of gene patents, but says too many genomics companies have participated in a land rush to file patents on genes for which they have not adequately identified functionality or use. Shuber also believes diagnostic test makers need to do a better job of explaining to payers, politicians and the general public why some tests are so expensive.

Exact Sciences currently markets a DNA-based test for hereditary colorectal cancer—PreGen-26 (priced at $495)—and hopes to launch another—PreGen-Plus—for general population colorectal cancer screening early next year. "We can defend the cost of our tests based on our investments in research and development, plus the laboratory costs associated with sample preparation, DNA purification and analytical time," Shuber says. Exact Sciences owns patents on its methods for detecting mutations and holds gene license agreements from Genzyme Genetics (Framingham, MA).

David Resnik, PhD, associate professor of medical humanities at the Brody School of Medicine, East Carolina University (Greenville, NC), expects no major changes to current U.S. laws covering gene patents. But he does anticipate incremental changes by government agencies and the courts to clarify free use of patented genes by research-only organizations. Resnik also anticipates higher hurdles to obtain gene patents. He thinks gene patent seekers will need to provide more details on the utility derived from their gene discoveries. The scope of new patents issued by the PTO will also become narrower in the future, according to Resnik. In the past, he points out, companies and research organizations would discover a gene, then immediately file for a patent even before clearly determining the precise use of the gene.

Rahul Dhanda, director of the bioethics program at Interleukin Genetics (Waltham, MA), believes genomic discovery companies have begun shifting their focus from filing thousands and thousands of patents to actually trying to

The genetic testing revolution is still in its early stages, but as more gene-based tests hit the market, expect the issue of gene patenting to get greater scrutiny

create revenue-generating diagnostics and drug therapies. Though he does not foresee dramatic changes to current gene patent laws, he notes that the genetic testing industry is still in its infancy, and political and public opinion could change as gene-based tests become more pervasive. Interleukin Genetics owns patents on three gene variants and is developing predictive tests for predisposition to certain diseases and for use in tailoring drug therapies.

Janet Reed, an attorney with Woodcock Washburn LLP (Philadelphia, PA), which helps academic research organizations file patents, says there is a strong contingent on the faculty and research side of academic institutions which contends that gene patents are impeding medical research. Reed also cites growing interest from the general public about gene patenting. "The political climate is good for the Rivers-Weldon legislation….It certainly stands a better chance of passing than it would have five years ago." However, she believes that any new laws that limit the strength of gene patents will also tend to weaken the overall U.S. patent system.

Lila Feisee, director for intellectual property at the Biotechnology Industry Organization (BIO-Washington, DC), says the Rivers-Weldon legislation, if enacted into law, would have a chilling effect on biotech research and development. Patents are often the only assets biotechnology companies have to attract the capital needed to develop lifesaving products, she argues. Of the roughly 1,100 companies and research institutions in BIO's membership, only about 5%-10% are profitable, she observes. "The majority of biotech companies are not walking away rich as a result of their gene patents."

Feisee says many of the recent discoveries that could be used as the basis for genetic tests are for extremely rare diseases. Commercial development of tests for these diseases would not happen without protections built into the patent system, she adds.

Ronley Plous, MD, president of Kaytron Corp. (Leawood, KS), a laboratory consulting firm, is adamant that companies have no more right to patent genes than they do to patent water or air. "I don't have a problem with a company like Myriad getting a fee for intellectual property associated with developing a testing technique or deciphering a genetic code. But I do have a problem when they claim ownership of a gene." Despite growing grass-roots opposition to gene patents, he doesn't anticipate any legal changes that would weaken patent protection. "It's a money-driven issue….The lawmakers are being swayed by the corporate lobbyists who favor gene patents."

Pam Sherry, vice president of investor relations at Laboratory Corp. of America (Burlington, NC), tells *DTTR* that gene patents have not been an obstacle to the company's efforts to expand its genetic testing menu. "Historically, we have gotten access to all the markers we have needed through licensing and royalty agreements."

Under an exclusive distribution agreement, LabCorp recently began selling gene-based tests developed by Myriad Genetics. LabCorp's 600-person sales force is marketing Myriad's tests to primary care physicians. Myriad's 100-person sales team will continue to focus on oncologists, ob/gyns, GI specialists and dermatologists.

Sales At Roche Diagnostics Up 7%; Igen Deal Not Imminent

Roche Group (Basel, Switzerland) reports that revenue at its Diagnostics Division grew 7% to 3.621 billion Swiss francs (US $2.424 billion) in the six months ended June 30, 2002, vs. 3.374 billion Swiss francs in the same period last year. EBITDA was up 6% to 982 million Swiss francs (US $657 million); operating profit was up 13% to 561 million Swiss francs (US $376 million).

Roche Diagnostics At A Glance
(in millions of Swiss francs)

	1st-Half 2002	% Chg
Total diagnostics revenue	3,621	+7
❖ Diabetes care	1,235	+10
❖ Near-patient testing	297	+4%
❖ Centralized diagnostics	1,301	+3%
❖ Molecular diagnostics	493	+16
❖ Applied science	295	+5
EBITDA	982	+6
Operating profit	561	+13

Source: Roche

Roche says growth was led by the molecular diagnostics unit, where revenue increased 16% to 493 million Swiss francs (US $330 million). PCR-based tests for hepatitis C and quantitative tests for HIV remained the top revenue earners, according to the company. During an Aug. 14 conference call, Heino von Prondzynski, head of the Diagnostics Division, said Roche anticipates launching a human papillomavirus (HPV) test in the U.S. in mid-2004. "HPV testing will be a main growth driver in the future….I expect this market to grow significantly over one billion Swiss francs [US $670 million] in the next 10 years."

Revenue from the centralized diagnostics unit was up 3% to 1.301 billion Swiss francs (US $871 million). Von Prondzynski said immunodiagnostics led the growth. Roche continues to proceed with its U.S. court appeal in its licensing dispute with Igen, he said, while at the same time the two are trying to reach an out-of-court settlement, "but are still very far apart" (*DTTR, Aug. '02, p. 1).*

Luminex CEO Resigns To Head Spin-Off

Luminex Corp. (Austin, TX) has agreed to spin off its Rules-Based Medicine research and development project (RBM) as a separate independent company that will be headed by Mark Chandler, PhD, Luminex's current chairman and CEO. Under the transaction, Luminex will receive an equity interest in the new company. Luminex will license certain technology and supply microspheres to the spin-off, which will focus on analyzing large numbers of proteins, metabolites and other substances in the blood of normal and diseased individuals.

In connection with the deal, Chandler will resign as chairman and CEO of Luminex, but will remain on its board of directors. Thomas Erickson, formerly with Omega Healthcare Investors (Timonium, MD), will serve as interim Luminex CEO until a long-term replacement for Chandler is found.

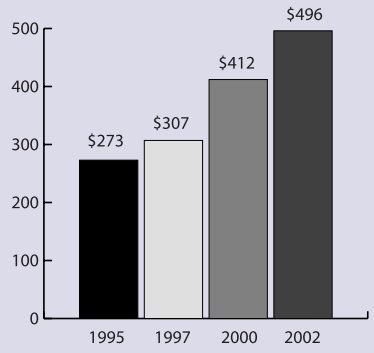
Chandler's departure comes as Luminex has struggled to commercialize its Luminex 100 system, a benchtop analyzer that performs up to 100 tests (including enzymatic, genetic and immunologic tests) simultaneously on one drop of fluid. In the three months ended June 30, 2002, Luminex recorded a net loss of $6.062 million vs. a net loss of $4.369 million in the same period a year earlier; revenue fell 33% to $3.177 million.

IVD Market In China Approaches $500 Million

China, currently the world's eighth-largest IVD market at nearly $500 million, will pass the United Kingdom and Spain within two years to become the world's sixth largest IVD market, according to Carl McEvoy, principal at the research and consulting firm of McEvoy & Farmer (San Francisco, CA) and the author of the 2002 edition of *China IVD Marketplace Guide*, his fourth such report over the last eight years.

China already is the world's second-largest market for most types of clinical laboratory instrumentation, says McEvoy, having passed Japan and Germany over the last three years. This year for example, 1,300+ routine chemistry autoanalyzers, 1,900+ automated hematology systems and 700+ automated immunoassay systems will be placed in China, the vast majority of them imported. At this point, 4,700 clinical labs in China have basic automation for their routine chemistry and hematology work. Another 3,300 are still working with semi-auto chemistry instruments and cell counters. Five thousand more work with manual photometers and microscopes. So, instrumentation markets should remain robust for years to come, McEvoy predicts.

China's IVD Market
(in MM, U.S. $$)



Source: McEvoy & Farmer

Because of China's entry into the World Trade Organization, reagent markets should start looking better to international companies as well. Until this year, China had been happy to import all the instrumentation it needed, but the reagent business was mostly directed to local firms. But international brands (both imported and locally produced) now account for 22% of routine chemistry reagent sales, 31% of immunochemistry reagent sales and nearly 48% of hematology reagent sales, McEvoy says.

Import duties will cease to be a relevant factor within three years, and local distributors will have much less leverage than they do today, as international firms will be able to own their distribution channels. The good news, says McEvoy, is that by 2005, most U.S. firms will finally be able to sell their reagents profitably in China. "The bad news is, the Chinese firms that survive the onslaught of international competition will by then be strong enough to hurt you everywhere else in the world."

Diametrics Seeks New Distribution Agreement With Philips

Diametrics Medical Inc. (Roseville, MN) says Philips Medical Systems, which is part of Royal Philips Electronics (Amsterdam, The Netherlands), has given notice of its plans to terminate its global distribution contract with Diametrics, effective Oct. 31, 2002. Andre de Bruin, chairman and interim CEO of Diametrics, says both companies are now trying to work out a new distribution agreement. Meanwhile, Diametrics, which makes the IRMA system for blood gas/electrolyte point-of-care testing, reported a second-quarter 2002 net loss of $2.131 million vs. a net loss of $1.027 million in the same period a year ago; revenue declined 14% to $5.276 million. Cash holdings totaled $3.6 million as of June 30.

i-Stat To Terminate Distribution Agreement With Abbott

i-Stat Corp. (East Windsor, NJ) has notified Abbott Laboratories (Abbott Park, IL) of its plans to resume direct distribution of its point-of-care blood analyzers, effective Jan. 1, 2004. Abbott has directly distributed i-Stat products in the U.S. and managed distributor relationships in all international markets (except Japan) since November 1998.

Under the current distribution agreement, Abbott gets a fixed percentage of all revenue derived from i-Stat analyzer and cartridge sales beyond i-Stat's pre-deal base of 4.5 million cartridge sales. In exchange for its distribution services, Abbott currently generates an estimated $4 million in revenue per quarter from i-Stat. After the distribution deal ends, i-Stat will keep this revenue.

i-Stat In Brief *($000)*

	2Q02	1Q01
Revenue	$14,780	$14,367
Operating loss	-3,897	-14,410
Net loss	-3,960	-14,222
Cash holdings	28,512	12,357

Source: i-Stat

To end the contract, i-Stat will have to pay a $5 million termination fee to Abbott in December 2003, plus $10 million for inventory reacquisition and certain other financial reconciliation items in early 2004. The company also will have to make some $55 million in residual payments to Abbott between 2004 and 2008.

During a July 25 conference call, Moffitt said i-Stat is expanding its direct sales force in preparation for the transition from Abbott. Over the past few months, i-Stat has added six new salespeople and now has a total of 10. Another two will be hired shortly, according to Moffitt. In addition, Moffitt says i-Stat will establish a clinical sales team to focus on expanding volume to existing customers. Finally, Moffitt notes that i-Stat recently hired Bruce Basarab as executive vice president of commercial operations, a new position for the company. Basarab was formerly senior vice president of sales and marketing for Geneva Pharmaceuticals, a $400 million unit of Novartis (Basel, Switzerland).

In the three months ended June 30, 2002, i-Stat reported a net loss of $4 million vs. a net loss of $14.2 million in the same period last year; revenue was up 3% to $14.8 million. Test cartridge sales increased 14% to 3.4 million units, but average revenue collected by i-Stat fell to $3.30 per cartridge from $3.47 a year ago. The average sales price to end-user customers was steady at approximately $4.45 per cartridge. Abbott collected an average of approximately $1.15 per cartridge sold ($4.45 minus $3.30=$1.15). Approximately 850 i-Stat systems were sold in the second quarter of 2002, bringing the worldwide installed base to 28,000 analyzers.

Of i-Stat's 3.4 million cartridges sold in the second quarter, 2.2 million were sold to U.S. customers, one million to international customers and 200,000 to the veterinary market. Moffitt says international sales are growing the fastest, citing China in particular, where cartridge sales have reached 750,000 on an annualized basis and are growing by more than 50% year over year. "The government in China is pumping a lot of money into building healthcare infrastructure….We see huge upside in this market."

In addition, Moffitt notes that i-Stat recently received clearance from the U.S. Food & Drug Administration for its prothrombin time test cartridge. The i-Stat analyzer now runs 14 tests and calculates another six parameters.

IVD Stocks Rise 2% In Latest Five Weeks

The 21 stocks in the G-2 Diagnostic Stock Index were up an unweighted average of 2% in the five weeks ended August 16, 2002, with 11 stocks rising in price and 10 falling. Year-to-date, the G-2 Index has fallen 28%, compared with a 19% decline for the S&P 500 and a 30% drop for the Nasdaq.

***Roche** non-voting equity shares, which trade on the Zurich stock exchange, are down 5% to 112.75 Swiss francs year-to-date. Shares of **Bayer**, which trade on the German stock exchanges, are down 33% to 23.91 euros per share year-to-date*

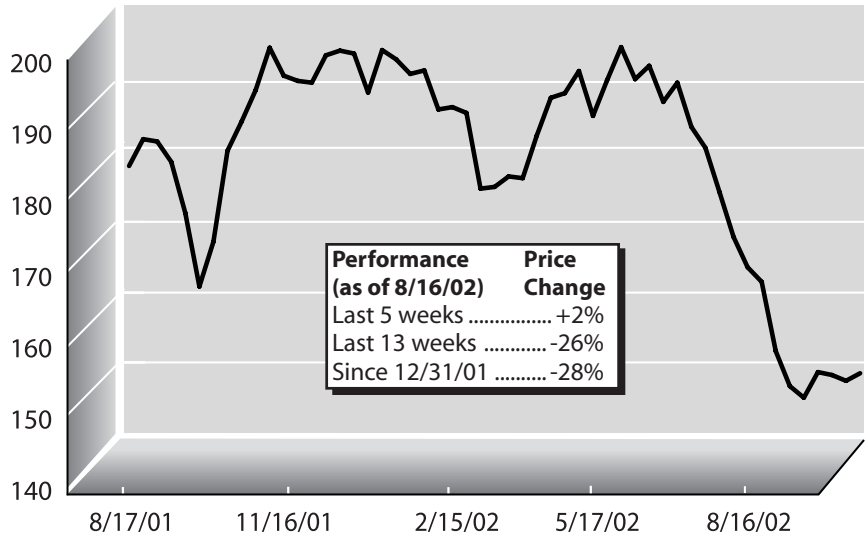
Shares of **Cholestech** (Hayward, CA) soared 29% to $12.56 per share for a market capitalization of $182 million. The company recently reported net income of $1.413 million for the three months ended June 28, 2002, vs. $1.245 million in the same period last year; revenue declined 7% to $11.568 million. Contributing to the revenue drop: termination of a major screening program with a single customer in the company's Wellcheck testing service business.

Shares of **Cytyc Corp.** (Boxborough, MA) rebounded after plunging on news that its planned merger with Digene was nixed by the Federal Trade Commission (*DTTR, Aug. '02, pp. 1, 5-7*). Shares jumped 24% to $10.30 per share for a market cap of $1.3 billion. The company recently announced an increase in its share repurchase program from $50 million to $100 million. As of June 30, Cytyc had $200.1 million in cash on its balance sheet.

Among other stocks rising: **Abbott Laboratories** (Abbott Park, IL), up 21% to $39.95 per share for a market cap of $63 billion; **Immucor** (Norcross, GA), up 17% to $26.90 per share for a market cap of $191 million; and **Meridian Bioscience** (Cincinnati, OH), up 17% to $6.82 per share for a market cap of $100 million.

Cygnus (Redwood City, CA) fell 68% to $0.71 per share for a market cap of $27 million. The company recently reported a net loss of $11.526 million for the three months ended June 30, 2002, vs. a net loss of $13.046 million in the same period last year; revenue was $316,000 vs. $71,000. Cash and investments totaled $17.3 million as of June 30.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 21 diagnostic test and equipment makers.

Avg. % Price Change, 5 weeks ended 8/16/02

UP		
Abbott Labs	39.95	+21
Bio-Rad	40.70	+4
Biosite	21.35	+3
Cholestech	12.56	+29
Cytyc	10.30	+24
Diagnostic Products	37.11	+8
Igen	33.21	+8
Immucor	26.90	+17
Johnson & Johnson	55.32	+10
Meridian	6.82	+17
Ventana	20.85	+9
DOWN		
Beckman Coulter	38.10	-14
Becton Dickinson	29.68	-1
Careside	0.08	-11
Cygnus	0.71	-68
Diametrics	2.60	-13
Digene	7.06	-3
Inverness Medical	15.70	-3
i-Stat	2.85	-2
Quidel	5.11	-6
TheraSense	15.00	-1

G-2 Insider

Scott Garrett

We find it interesting that Jack Wareham, the chairman and CEO of Beckman Coulter (Fullerton, CA), chose Scott Garrett to replace Albert Ziegler as head of the company's $1.4 billion clinical diagnostic division (*DTTR, July '02, p. 8*).

It was Garrett, after all, who kicked off the IVD industry's painful consolidation era back in 1994 when he convinced Bain Capital and Goldman Sachs to pony up $444 million, so he could buy Baxter Diagnostics—his fiefdom within the Baxter Group at that time—to create Dade Diagnostics. As CEO of Dade, Garrett then bought DuPont's IVD business for $586 million in May 1996. About a year later, Dade acquired the IVD business ("Behring") of Hoechst AG and was christened Dade Behring. Shortly thereafter, Garrett got the boot as it became apparent to Bain and Goldman that Garrett was more adept at deal-making than operating the far-flung, debt-laden behemoth he had created.

For the next few years, he worked in relative obscurity as head of his own investment firm and as CEO of Kendro Laboratory Products, LP, which was acquired last year by SPX Corp. (Muskegon, MI).

Now, with his new position at Beckman, Garrett is back in the big leagues. And that leads this industry observer to wonder if Wareham, who at 60 is nearing retirement age, has promised Garrett the keys to the kingdom in the not-too-distant future. But which kingdom? Was Garrett hired to buy something big, sell something big or both (at the same time)?

Think I'm all wet? You can contact me at *labreporter@aol.com.*

Jondavid Klipp, managing editor

Company References

American College of Medical Genetics 301-530-7127

Bayer Diagnostics 914-631-8000

Beckman Coulter 714-871-4848

Biotechnology Industry Organization 202-962-9200

Dade Behring 847-267-5300

Diametrics 651-639-8035

Exact Sciences 978-897-2800

Interleukin Genetics 781-398-0700

i-Stat 609-443-9300

Kaytron Corp. 913-663-5298

LabCorp 336-584-5171

Luminex 512-219-8020

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Roche Diagnostics 317-849-9350

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