

Edgar Filing: IGEN INTERNATIONAL INC /DE - Form 8-K

IGEN INTERNATIONAL INC /DE

Form 8-K

July 10, 2003

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 8-K  
CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported: July 9, 2003):

IGEN INTERNATIONAL, INC.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other Jurisdiction of  
Incorporation)

0-23252  
(Commission File Number)

94-2852543  
( I.R.S. Employer Identification No.)

16020 Industrial Drive  
Gaithersburg, Maryland 20877  
(Principal Executive Office) (Zip Code)

Registrant's telephone number, including area code: (301) 869-9800

Exhibit Index on Page 4

Item 5. Other Events

On July 9, 2003, IGEN International, Inc. ("IGEN") announced that the U.S. Court of Appeals for the Fourth Circuit affirmed IGEN's right to terminate the License

## Edgar Filing: IGEN INTERNATIONAL INC /DE - Form 8-K

and Technology Development Agreement dated as of September 23, 1992 (the "License Agreement"), between IGEN and Roche Diagnostics GmbH ("Roche"), a division of F. Hoffman-LaRoche. IGEN has notified Roche that the License Agreement has terminated. The Court of Appeals also affirmed IGEN's right to certain improvements developed by Roche under the License Agreement, including Roche's Elecsys(R) diagnostics product line.

In addition, the Court of Appeals reversed the portion of the judgment that held Roche liable for unfair competition, thus vacating the \$400 million punitive damage award against Roche. The ruling also reversed \$86.8 million in compensatory damages and left intact IGEN's right to over \$18 million in compensatory damages for unpaid royalties, out-of-field-sales and withholding of improvements.

Termination of the License Agreement ends Roche's rights under the license from IGEN to manufacture, market, and sell ORIGEN-based products, including its Elecsys 1010 and 2010 instruments and assays. In addition, Roche is no longer licensed to sell the Elecsys E170 product line, which has been integrated into Roche's MODULAR ANALYTICS system. This system couples together Roche's clinical chemistry systems with the Elecsys E170 immunoassay systems and a series of other modules. In addition, IGEN will receive specified rights to certain improvements relating to the Elecsys product line, as well as to certain other improvements licensed, owned or developed by Roche, including PCR, a nucleic acid amplification technology.

Also on July 9, 2003, IGEN filed patent infringement lawsuits against Roche in the United States and Germany to ensure that Roche ceases any further sales of products that incorporate IGEN's ORIGEN technology. IGEN filed an action in the U.S. District Court for the District of Maryland seeking a finding that Roche is infringing IGEN's ORIGEN patents, as well as a preliminary and permanent injunction against Roche's further infringement of those patents. A similar lawsuit was simultaneously filed in Germany.

A copy of the opinion can be found on the website of the U.S. Court of Appeals for the Fourth Circuit at <http://pacer.ca4.uscourts.gov/opinion.pdf/021537.P.pdf>

IGEN also intends to post a copy of the opinion on its website at [www.igen.com](http://www.igen.com) and will file it with the SEC as soon as reasonably practicable.

### Cautionary Note About Forward-Looking Statements

This Form 8-K contains forward-looking statements within the meaning of the "safe harbor" provision of the Private Securities Litigation Reform Act of 1995. All statements that are not statements of historical fact are forward-looking statements. The words "may," "should," "will," "expect," "could," "anticipate," "believe," "estimate," "plan," "intend" and similar expressions have been used to identify certain of the forward-looking statements in this Form 8-K. We have based these forward-looking statements on management's current expectations, estimates and projections and they are subject to a number of risks, uncertainties and assumptions which could cause actual results to differ materially from those described in the forward-looking statements. The following factors are among those that may cause actual results to differ materially from our forward-looking statements: the outcome of the Roche litigation and our relationship with Roche Diagnostics GmbH; our ability to develop and introduce new or enhanced products; our ability to enter into new collaborations on favorable terms, if at all; our ability to expand the commercialization of existing products; our ability to expand our manufacturing capabilities or find a suitable manufacturer on acceptable terms or in a timely manner; our ability to develop our selling, marketing and distribution capabilities; our and our licensees' ability to obtain FDA and other governmental approvals for our and their clinical testing products; the ability of our licensees to effectively develop and market products based on the technology we license to them; domestic

## Edgar Filing: IGEN INTERNATIONAL INC /DE - Form 8-K

and foreign governmental and public policy changes, particularly related to health care costs, that may affect new investments and purchases made by customers; availability of financing and financial resources in the amounts, at the times and on the terms required to support our future business; rapid technological developments in each of our markets and our ability to respond to those changes in a timely, cost-effective manner; protection and validity of patent and other intellectual property rights; and changes in general economic, business and industry conditions. These and other risk factors are discussed in IGEN's annual report on Form 10-K for the year ended March 31, 2003, filed with the Securities and Exchange Commission (SEC) and available at the Investor Relations section of IGEN's web site at [www.igen.com](http://www.igen.com) or the SEC's web site at [www.sec.gov](http://www.sec.gov). IGEN disclaims any intent or obligation to update any forward looking statements.

### Item 9. Regulation FD Disclosure

On July 9, 2003, IGEN issued the press release attached to this Form 8-K as Exhibit 99.1, announcing the decision of the U.S. Court of Appeals for the Fourth Circuit in IGEN's litigation with Roche. The information provided in Item 9 of this Form 8-K, including Exhibit 99.1, shall not be deemed to be incorporated by reference into IGEN's filings with the SEC under the Securities Act of 1933.

### EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by the registrant, dated July 9, 2003.

### SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 10, 2003

IGEN INTERNATIONAL, INC.

By: /s/ George V. Migausky

-----  
Name: George V. Migausky  
Title: Vice President and Chief Financial  
Officer (Principal Accounting Officer)