LAW OFFICES
TOWNSEND AND TOWNSEND

STEPHEN S. TOWNSEND
ANTHONY B. DIEPENBROCK
DIRKS B. FOSTER
THOMAS F. SMEGAL, JR.
WILLIAM MICHAEL HYNES
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KENNETH R. ALLEN
DAVID N. SLONE
LESLEY S. WITT
ROBERT C. COLWELL

MARK MOHLER
J. THOMAS McCARTHY
OF COUNSEL

PATENTS, TRADEMARKS, AND COPYRIGHTS

TWENTIETH FLOOR
STEUART STREET TOWER
ONE MARKET PLAZA
SAN FRANCISCO, CALIFORNIA 94105
(415) 543-9600
CABLE "DEWEY"
TWX
910-372-6566
TOWNSEND SFO

PALO ALTO OFFICE
NUMBER FIVE PALO ALTO SQUARE
3000 EL CAMINO REAL
PALO ALTO, CALIFORNIA 94304
(415) 493-2590

CHAS E. TOWNSEND (1904-1944)

August 4, 1980

Thomas G. Ferris, Esq.
Patent Attorney
Patent Branch
c/o NIH
5A-03 Westwood Building
Bethesda, Maryland 20014

Re: University of Colorado IPA
Investigation re U.S. 4,188,159
Our File No. 2558-101

Dear Mr. Ferris:

In line with my telephone conversations with you earlier this month, I am now writing on behalf of our client, Bio-Rad Laboratories, to request that your office investigate what we believe to be a breach of the government's Institutional Patent Agreement (IPA) with the University of Colorado.

In an apparent violation of Section VII of the IPA, the University has assigned U.S. Patent No. 4,188,159 (the Allen patent) to University Patents, Inc. (UPI), a patent management group, pursuant to a patent administration contract which does not make such a transfer of rights subject to any of the terms and conditions of the IPA between the University and HEW.

Moreover, the invention of the Allen patent is not being administered in the public interest as required by Section VI(c) of the IPA. UPI is demanding a royalty rate which is unreasonable under the circumstances and demonstrably in excess of normal trade practice for the particular diagnostic test involved, a violation of both Section VI(c) and Section VI(e) of the IPA. If given the opportunity we will provide evidence that the industry standard for an invention such as that of the Allen patent is a 1% royalty rate. In fact, the

Allen patent is only one of four separate inventions which may be practiced for commercial B-12/Folate diagnostic testing. Patents on at least two of the other three inventions are available to the industry on a non-exclusive basis at a 1% royalty. The Allen patent is being offered by the patent management group of the University of Colorado at a royalty rate of 3-4%.

While we cannot know for certain, we assume that each of the companies on the attached list would be able to provide you with evidence supportive of our position that a 1% royalty rate is normal trade practice in regard to the patentable aspects of the B-12/Folate serum tests.

As we understand the situation, where an invention is the result of government funds provided through a university, the government agency involved in that funding, whether or not it has waived title in favor of the university, has the right and duty to assure that the invention is managed in the public interest and to see that it is offered for licensing at a reasonable royalty rate. We believe that with regard to the Allen patent HHS, as the contracting government agency, has the duty to enforce the provisions of its IPA with the University of Colorado.

In addition to investigating the above described breach of the University's IPA, your office should consider an exercise of its rights under Section XII(b) of the IPA with the University of Colorado in regard to the Allen patent. Under Section XII(b), the government may license or require the licensing of others on a royalty-free basis or on terms that are reasonable under the circumstances if, inter alia, the invention is required for public use by governmental regulation. The labeling requirements prescribed for diagnostic tests by the Food and Drug Administration effectively mandate industry-wide use of the invention of the Allen patent.

During our telephone conversation of June 30, 1980, you indicated that HHS has no formalized procedures for handling reported IPA violations or requests to exercise "march-in" rights under its IPAs. As such, I would appreciate it if you could provide some insight into the administrative

procedure you anticipate following should we file a formal petition with HHS.

Sincerely,

TOWNSEND and TOWNSEND

Lesley S. Witt

LSW:pfr
cc: Gordon Reese, Patent Administrator
University of Colorado
Senator Birch Bayh, Chairman
Subcommittee on the Constitution
Senator Gaylord Nelson, Chairman
Select Committee on Small Business

INTERESTED PARTIES FROM
DIAGNOSTIC TESTING INDUSTRY

Becton-Dickinson and Company
Immunodiagnostics
Mountain View Avenue
Orangeburg, NY 10912

RIA Products, Inc.
P. O. Box 914
97 Beaver Street
Waltham, MA 02154

Clinical Assays
620 Memorial Drive
Cambridge, MA 02139

New England Nuclear
Treble Cove Road
North Billerica, MA 01862

Diagnostic Products, Inc.
12306 Exposition Boulevard
Los Angeles, CA 90064

Union Carbide
Medical Products Division
Clinical Diagnostics
270 Marble Avenue
Pleasantville, NY 10570

Amersham
2636 S. Clearbrook Drive
Arlington Heights, IL 60005