

REPORT

SIERRA LEONE LECTURE SERIES ON U.S. BIOTECHNOLOGY AND PHARMACEUTICAL LAW AS PART OF THE RECOVERING NATIONS PROJECT

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Presented jointly by

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EXECUTIVE SUMMARY

The first Sierra Leone lecture series on U.S. biotechnology and pharmaceutical law was presented in Freetown during November, 2004 as part of the Recovering Nations Project. The series, including three lectures in all, introduced to academic audiences the topics of U.S. patent and regulatory law as they relate to biotechnology and pharmaceuticals. These lectures are germane to AIDS drug access in Africa, and were presented in this war-ravaged country as a way of aiding its recovery through professional engagement with foreign nationals.

INTRODUCTION

Recovering Nations and the Need for Professional Exchange

International assistance for recovering nations is typically provided in order of greatest urgency, e.g., food, medical care, financial aid and peacekeeping assistance. To the extent international attention is paid to legal development in recovering nations, subjects such as constitutional and criminal law are usually given the most attention.

When considering a nation recovering from a cataclysm, certain things should be noted. First, a nation's population prior to a cataclysm such as civil war is invariably multifaceted with respect to geography, lifestyle, education, profession, wealth and position of influence within society, to name a few examples. Second, a cataclysm normally affects different groups differently – both qualitatively and quantitatively. Third, barring the unusual scenario where an entire educated class is targeted for destruction (as in Cambodia during the late 1970's), many if not most of the educated people survive, and eventually desire to progress professionally.

Typically, it is the educated class in a recovering nation that is charged with leading its recovery – whether through procuring international assistance or coordinating the rebuilding effort using domestic resources. It makes sense, therefore, that the task of creating new professionals and expanding the talents of existing ones should occur as soon as possible, and should not be delayed until the task of obtaining more “essential” support such as food and medical aid has been completed.

Given this, it makes sense that recovering nations would benefit from professional exchange with other countries, while concurrently benefiting from more urgently needed international support.

Biotechnology and pharmaceutical law is practiced almost exclusively in wealthy nations such as the U.S., Canada, Japan, Australia and certain European countries. Far less attention is paid to it in the developing world and, in recovering nations, even less – if any – attention is paid. Despite this, however, biotechnology and pharmaceutical law and policy, always deemed important in wealthier nations, can have considerable relevance in

less fortunate parts of the world. Recent events in South Africa regarding the availability of anti-AIDS drugs, and in Zambia regarding the use of genetically modified food, underscore this point.

For these reasons, professional engagement in the biotechnology and pharmaceutical law sector would benefit those in recovering nations.

Recovering Nations Project

Understandably, yet regrettably, the need for professional exchange as a part of the recovery process is often ignored by the international community. To help fill this gap, the Recovering Nations Project was created to provide professional education to appropriate audiences in the world's recovering nations, through lectures and informal discussions on biotechnology and pharmaceutical law as well as other areas of law less practiced in recovering nations.

The Choice of Sierra Leone for the First Lecture Series

The small West African nation of Sierra Leone gained independence from Great Britain in 1961. The country boasts both natural wealth, particularly in the form of diamonds, and at least historically, a reputation as a center of higher education throughout West Africa.

Since independence, Sierra Leone's situation steadily deteriorated and, in 1991, the country was plunged into a civil war which lasted until 2002. The civil war – one of the most brutal ever witnessed – horrified Sierra Leoneans and the international community alike. The combatants, particularly the Revolutionary United Front, committed every form of atrocity, including randomly amputating the hands of thousands of innocent men, women and children. It was these amputations which ultimately became the war's hallmark.

Today, with the war formally over, Sierra Leone is a nation desperately in need of recovery. It presently ranks 177th out of the 177 countries listed in the United Nations 2004 Human Development Index. The country is characterized by an average life-span of 34.3 years, a per capita GDP of \$520, and a literacy rate of 36%.

Despite these grim facts, Sierra Leone today enjoys relative peace and stability throughout the country. It also has a small yet highly-educated and worldly population of professionals in its capital Freetown, as exemplified by the nearly 100 practicing attorneys there.

For all of these reasons, Sierra Leone was chosen for the Recovering Nations Project's first lecture series.

THE LECTURE SERIES

In all, the series consisted of three well-attended lectures, accompanied by the contribution of legal texts and other materials as described in detail below. The first lecture, delivered at the National School of Nursing on November 22nd, was attended by medical, pharmaceutical and nursing students and faculty. The second lecture was delivered on November 23rd to the students and Director of Sierra Leone Law School. The third lecture was delivered on November 24th to undergraduate law and science students at Forah Bay College, the country's oldest and most prestigious college.

Each lecture introduced the fundamentals of U.S. patent and regulatory law as they relate to the biotechnology and pharmaceutical industries. Patent law topics covered included the purpose and anatomy of a patent, the requirements for patentability, and the fundamentals of patent prosecution, licensing and enforcement. Regulatory law topics included an overview of drug development, clinical testing and FDA approval processes, and a discussion of the interplay between brand-name and generic drug companies. The lectures were followed by in-depth discussions of the lecture topics, particularly as they relate to AIDS drugs in sub-Saharan Africa.

CONTRIBUTED LEGAL TEXTS

Each of the following legal texts was contributed to the Law Library of Forah Bay College at the University of Sierra Leone, and the Library of the Sierra Leone Law School.

Jeffery M. Samuels, PATENT, TRADEMARK AND COPYRIGHT LAWS, The Bureau of National Affairs (2004).

Herbert F. Schwartz, PATENT LAW AND PRACTICE, The Bureau of National Affairs (2003).

Kenneth J. Burchfiel, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT, The Bureau of National Affairs (1997).

Dale H. Hoscheit and Lisa M. Hemmendinger, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT 2000 CUMULATIVE SUPPLEMENT, The Bureau of National Affairs.

Randy Berholtz and S. Peter Ludwig, BIOTECHNOLOGY LAW 2003: BIOTECHNOLOGY PATENTS & BUSINESS STRATEGIES, The Practicing Law Institute.

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, BIOTECHNOLOGY INNOVATION REPORT 2004: BENCHMARKS.

Laurence H. Pretty, PATENT LITIGATION, The Practicing Law Institute.

Donald O. Beers, GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS, Aspen Publishers.

CONTRIBUTED ARTICLES AND PRESENTATIONS

Each of the following articles and presentations was made available to the lecture attendees:

BIOTECHNOLOGY: UNDERSTANDING THE IMPACT OF AN FDA REGULATORY STRATEGY, presented at *Running the Race with Biotechnology: From Start to Finish*, March 8 and 9, 2004, San Diego, California; by Mark S. Brown, Esq., King & Spalding, LLP.

HATCH-WAXMAN REFORMS UNDER THE “MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT 2003”, presented at *Running the Race with Biotechnology: From Start to Finish*, March 8 and 9, 2004, San Diego, California; by Brian V. Slater, Esq., Fitzpatrick, Cella, Harper & Scinto, LLP.

BIOTECH LICENSING AGREEMENTS, presented at *Running the Race with Biotechnology: From Start to Finish*, March 8 and 9, 2004, San Diego, California; by Roger M. Tolbert, Esq., Orrick, Herrington & Sutcliffe, LLP.

INVENTORS AND THEIR ATTORNEYS MUST BEWARE OF THEIR ACTIONS BEFORE THE U.S. PATENT & TRADEMARK OFFICE, presented at *Running the Race with Biotechnology: From Start to Finish*, March 8 and 9, 2004, San Diego, California; by Richard Warburg, Esq. and Lauren Nguyen, Esq., Foley & Lardner.

THE BIOPHARMACEUTICAL SECTOR OF BIOTECHNOLOGY: HISTORY, SCIENCE AND BUSINESS, presented at *Biopharmaceuticals: Running the Race from Drug Discovery to Commercialization*, May 3 and 4, 2004, Raleigh, North Carolina; by David Harper, Esq., Ph.D., McDonnell, Boehnen, Hulbert & Berghoff.

DO PATENTS FOR ANTIRETROVIRAL DRUGS CONSTRAIN ACCESS TO AIDS TREATMENT IN AFRICA? by Amir Attaran, D.Phil, LLB and Lee Gillespie-White, LLB, Center for International Development, Harvard University.

SELECTED MATERIALS FROM ADVANCED TRAINING COURSE IN U.S. PHARMACEUTICAL PATENT PRACTICE, presented at: *The Advanced Training Course in U.S. Pharmaceutical Patent Practice*, held under the auspices of the Ministry of Technology, Guangzhou, China, September 21-25, 1998; by Alan J. Morrison, Esq., Cooper & Dunham LLP and Albert Wai-Kit Chan, Esq., then of Cooper & Dunham LLP.

NON-PATENT PROTECTION FOR BIOTECHNOLOGY AND PHARMACEUTICALS, presented at: *Running the Race with Biotechnology: From Start to Finish*, March 8 and 9, 2004, San Diego, California; by Alan J. Morrison, Esq. and Maria V. Marucci, Esq., Cooper & Dunham LLP.

SELECTED PORTIONS OF THE PLAYERS: PRESENT MODELS FOR DRUG DEVELOPMENT, presented at: *Biopharmaceuticals: Running the Race from Drug Discovery to Commercialization*, May 3 and 4, 2004, Raleigh, North Carolina; by Geoff Erickson, A.M. Pappas & Associates.

SPEAKER'S BIOGRAPHY

Alan J. Morrison is a partner at the firm of Cooper & Dunham LLP in New York. Mr. Morrison's practice includes all aspects of U.S. and international patent prosecution in the biotechnology and pharmaceutical areas, as well as opinion work relating to patentability, infringement and invalidity. His practice also encompasses preparing biotechnology-related contracts such as licenses, joint development agreements, feasibility study agreements and technology transfer agreements, and counseling clients regarding the negotiation of these contracts. Prior to joining Cooper & Dunham, Mr. Morrison was in-house counsel at Johnson & Johnson, and associate attorney at the New York firm of Rogers & Wells. Mr. Morrison earned his B.A. in biochemistry from U.C. Berkeley, his M.S. in biological chemistry from the University of Michigan, his M.Phil. in biochemistry and molecular biophysics from Columbia University, and his J.D. from Yeshiva University. He is registered to practice before the U.S. Patent and Trademark Office, and is a member of the American Bar Association and the American Intellectual Property Law Association. Mr. Morrison lectures both domestically and internationally on topics in U.S. patent law such as biotechnology and pharmaceutical law, inventorship determination, claim drafting, and intellectual property aspects of mergers and acquisitions. Mr. Morrison has a long-standing interest in foreign affairs, particularly in developing nations, and has traveled to many such countries in Asia, Latin America and Africa.

ROBERTS & PARTNERS

Roberts & Partners is a relatively new firm, yet is now ranked as one of the top five law firms in Sierra Leone and is the country's largest. Roberts & Partners has grown from an initial founding partnership of three partners to now include two associates and a legal officer, all qualified to practice as Barristers-at-Law and Solicitors. Its lawyers can call upon many years of experience gained in private and institutional practice, including practice in the offices of the Attorney General & Solicitor General of Sierra Leone and other law firms prior to forming Roberts & Partners. Since its inception, the firm has represented a wide range of clients, such as government and quasi government departments and agencies, corporations, foreign investors and sovereign states.

Roberts & Partners presently collaborates with law firms, consulting firms and energy firms in the U.S., Africa and Europe. The firm has consulted for the European Union and now consults for the World Bank and the International Finance Corporation in a number of areas.

It is the firm's hope that lectures by foreign professionals will be held in Sierra Leone with increasing frequency in the future. In this regard, Roberts & Partners is committed

to working with foreign academicians and practitioners interested in sharing their legal expertise with relevant audiences in Sierra Leone.

The firm's Senior Partner, Emmanuel E. Roberts, is a part-time lecturer on civil procedure with the Council of Legal Education, the statutory body that conducts examinations for those wishing to be admitted to the Sierra Leone Bar. The Managing Partner, Centus O. Macauley, is a part-time lecturer of business law, English law and European Union law at the University of Sierra Leone, Institute of Public Administration & Management.

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Dr. Len Gordon-Harris, Principal, College of Medical and Allied Health Sciences, for his helpful insights regarding Sierra Leone's medical community and the potential benefits of international professional exchange in the country's recovery.

Ambassador Joe Robert Pemagbi, Sierra Leone's Permanent Representative to the United Nations, for his helpful insights regarding Sierra Leone's political situation and the need for interaction with foreign professionals.

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James Stewart, Deputy Chief of Mission, United States Embassy in Sierra Leone, for his helpful insights regarding Sierra Leone's political situation, U.S.-Sierra Leone relations, and the potential role of U.S. professionals in Sierra Leone's recovery.