HEALTH-RELATED PATENTS IN THE LOUISVILLE AREA 1996-2002

A STUDY CONDUCTED BY THE HEALTH ENTERPRISES NETWORK

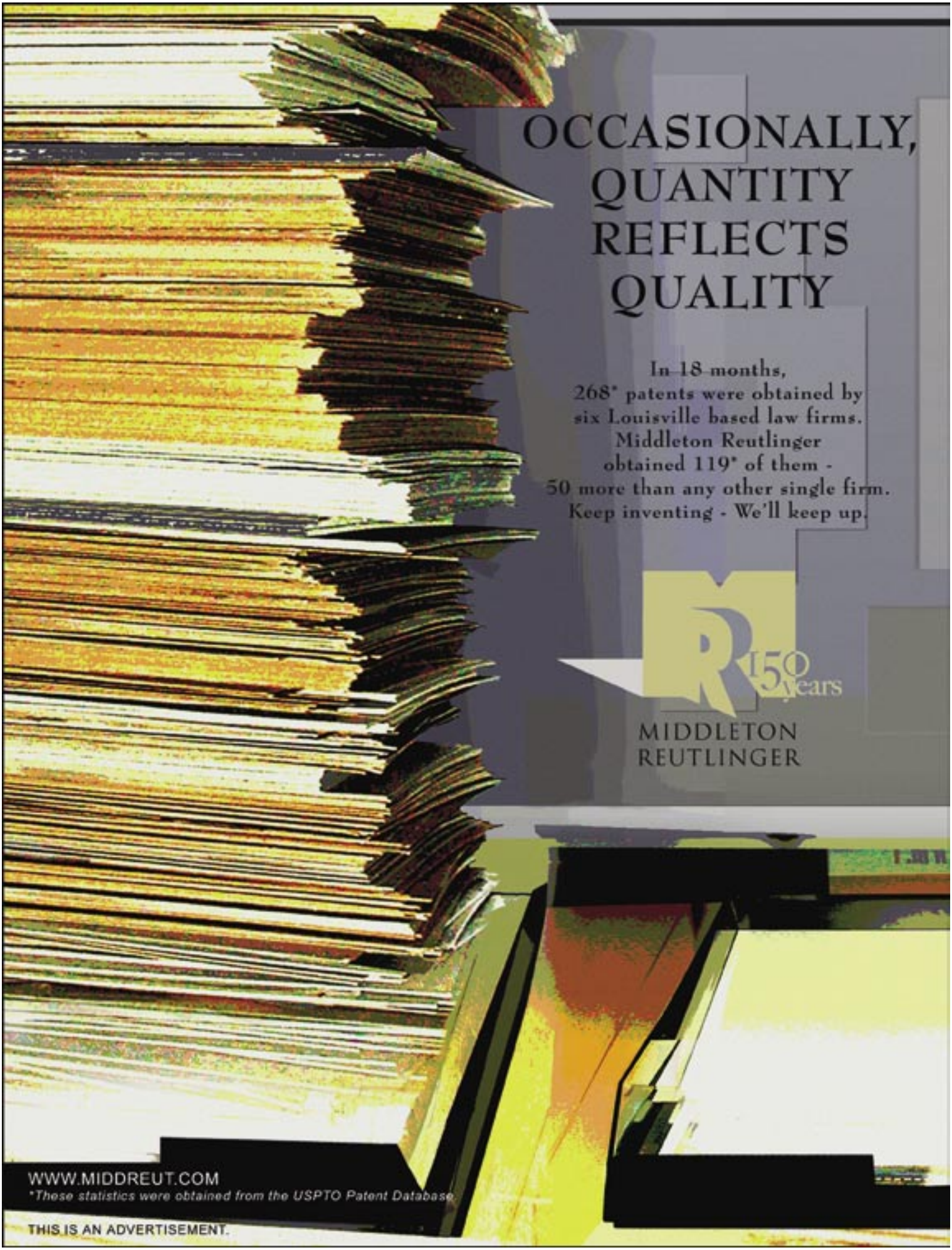
HealthEnterprisesNetwork | Louisville

A Greater Louisville Inc. Affiliate

Fostering the Growth of the Region's Health-Related Economy

Sponsored by:

MIDDLETON REUTLINGER


OCCASIONALLY,
QUANTITY
REFLECTS
QUALITY
In 18 months,
268* patents were obtained by
six Louisville based law firms.
Middleton Reutlinger
obtained 119* of them -
50 more than any other single firm.
Keep inventing - We'll keep up.
150 years
MIDDLETON
REUTLINGER
WWW.MIDDREUT.COM
*These statistics were obtained from the USPTO Patent Database.
THIS IS AN ADVERTISEMENT.

HEALTH-RELATED PATENTS IN THE LOUISVILLE AREA 1996-2002

A STUDY CONDUCTED BY THE HEALTH ENTERPRISES NETWORK

Table of Contents

Introduction

The Health Enterprises Network is an economic development group formed by the leadership of Louisville's health-related businesses, from hospitals and health services companies to physicians, medical device manufacturers and professional service providers. Our vision is for the region to be globally recognized as a "location of choice" for health-related businesses, researchers, educators, investors and consumers. Our mission is to champion and foster the growth of the region's health-related economy.

This study on patent activity in the region serves several purposes: document our strengths in intellectual property creation, recognize those areas most actively invented by our scientists, celebrate the success of our community's entrepreneurs and inventors and encourage more activity in fields with a high degree of local talent. Since innovation and entrepreneurism is a key ingredient in economic growth, it is important for the Network to catalog the number of health-related patents from our area. With this data, the Network can help facilitate government affairs initiatives and workforce/talent development programs that encourage more entrepreneurial activity and investment in the most active sectors of the region's thriving health-related economy.

Background

Our region – This document tracks patents by researchers living in Louisville's 24-county workforce region, filed at the United States Patent and Trademark Office (USPTO) in Washington, D.C. In all, more than 1,100 patents have been filed from this region over the seven years we studied. Dr. Dave McClure, Esq. and the late-Professor Arno Spatola, one of Louisville's greatest inventors, scholars and educators, helped add credibility to this report by reviewing summaries from USPTO records and guiding our research methodology. We are deeply indebted to these individuals. Not only did they help determine which of these 1,100 patents were "health-related," but they added a great deal of insight into the capabilities and limitations of this undertaking.

A patent – as defined by the USPTO – is a property right granted by the Government of the United States of America to an inventor "to exclude others from making, using, offering for sale or selling the invention throughout the United States or importing the invention into the United States" for a limited time in exchange for public disclosure of the invention when the patent is granted. While patents offer a significant set of rights, they do not meet every situation and, in fact, are more and more limited by ever-increasing costs. This is exacerbated by the significant time delays and the need to file in several international jurisdictions.

While patents only represent one segment of intellectual property classifications, it is the classification most widely recognized by the public and generally has only one coordinating office in each country, also making them the easiest to track. Copyrights, trademarks and service marks are difficult to track, as some need not be formally filed to be in effect. Additionally, many have different laws and regulations among each of the 50 states. Trade secrets, by their very nature, must remain secret and also lack a centralized office for recording even a generalized summary of the type of secret being kept.

In addition to the sheer number of patents to study, this process was made more challenging by two important factors. First, the geographic origin of a patent is tracked by the home city and state of the person listed as the primary inventor on the patent filing. This means each individual small city must be tracked and that co-inventors from other locations (who may have contributed a great deal to the invention) are listed, but the patent is not attributed to their home city. Because of this systemic quirk, only a portion of the intellectual capital in Louisville is recognized in this report. Second, summaries of patents and formal patent filings can be very complicated and difficult to comprehend. We encourage researchers who were not included in this document to give us feedback on how to improve this report.

Summary of Results

In all, 165 "health-related" patents were filed from the region from 1996-2002. These patents represent two core scientific areas, six industry sectors and 22 medical areas.

Of the two core scientific areas – engineering and chemistry – engineering was the dominant area for patents. Nearly four of every five patents (78.8 percent) were for a product that was engineered.

Not coincidentally, devices overwhelmingly led the industry sectors, far outpacing agriscience, biotech, pharmaceutical, service and software patents. Nearly three of every four patents (74.5 percent) were for a new device.

Also not coincidentally, the region's known strengths in certain medical areas dominated. Thirty-eight patents were filed in the field of ophthalmology (we were initially surprised by the number of ophthalmology patents although it stands to reason after thinking of Louisville's resources in the field and accounting for one very prolific inventor who studied under Dr. Arno Spatola) Twenty-two were filed in cardiology; 16 were filed in orthopedics; and 25 were filed in non-specific areas.

Of the patents, 79 were owned by companies in the Louisville area and 62 were owned by companies outside the region at the time the patent issued. The remainder were owned by the inventor. Companies and organizations utilizing locally produced patents include Colgate-Palmolive, Duke University, Guidant Corp. and the United States Air Force. Strict ownership or "assignment" of a patent is becoming less popular than "licensing" a patent for use by another entity for a specific purpose over a defined time frame. Unfortunately, it is not possible to accurately and completely track licenses.

During the seven-year span, patent activity was at its busiest in 1999 and 2000 when 31 patents were approved each year. While the number of approvals has declined since, it is important to note that the number of applications received by the USPTO has created a significant backlog in the approval process. Also, the need for patent filings in various international locations has increased the potential cost dramatically, as has the ever-increasing number of patents that must be reviewed prior to finalizing a patent application. It is possible that the decline in patent activity may just be a statistical aberration, one that is likely to change for the better with an increase in scholars in Kentucky from the Bucks for Brains program, an increase in activity from the newly enhanced Technology Development Office at U of L, the presence of two new university presidents in Kentucky each with a keen focus on the economic development mission of their respective university and a burgeoning life science industry that will no doubt spawn more property creation at the first signs of success.

It needs to be stressed that Bucks for Brains researchers who came from research positions at other universities have mature research that has produced intellectual property. While this is a strong benefit of the program, it will require more time before a report such as ours will show this benefit (since it can take up to 90 months for a patent to issue). Also, many of these scholars were recruited after 1999 and already had patent applications in process at their previous institutions. It is likely that the USPTO will record those patents as invented at the prior locations.

U of L is now tying patent production to pay raises and tenure decisions. In addition, the school has added a technology development office, which should aid in the transferring of patents to commercial outlets. These are moves that should significantly bolster the amount of patents produced in the region.

Ophthalmology in Louisville

A major emphasis on ophthalmology research in Louisville began in 1963 when a group of renowned vision scientists was brought to the University of Louisville under the leadership of the late-Professor Hugh Davson. A capital campaign led by the Kentucky Lions Eye Foundation made it possible to build the Kentucky Lions Eye Research Institute, which opened in 1969 at the corner of Floyd and Muhammad Ali (then Walnut) Streets. This facility attracted national and international researchers to the area to perform clinical and basic eye research.

The U of L School of Medicine's Department of Ophthalmology and Visual Sciences (DOVS) and the Kentucky Lions Eye Center (KLEC, formerly the Kentucky Lions Eye Research Institute) have played integral roles in the growth of laboratory and clinical research activity in Louisville. Research at KLEC has flourished under the leadership of many notable figures such as 10-year Chair Albert Potts, M.D., Ph.D.; Chairman Thom Zimmerman M.D., Ph.D.; Professor and Director of Research Christopher Paterson, D.Sc.; and most recently Henry J. Kaplan, M.D., who is the Evans Professor of Ophthalmology, Chairman of the DOVS and Director of the KLEC. During Drs. Zimmerman and Paterson's tenure, 15 full-time faculty were recruited and funding generated by National Eye Institute grants increased 250% to more than $2 million. Currently, Dr. Kaplan has recruited eight new vision scientists to the faculty, four of whom were former colleagues at Washington University. Under his direction, the DOVS is now in the top 10 in the nation for funding from the National Eye Institute with over $6 million in vision research funding for the University of Louisville for 2003. He seeks to further develop three areas – retinal degeneration, ocular immunology and uveitis.

Other researchers have contributed greatly to the development of Louisville's ophthalmology resources. Since the 1980's, Dr. Norman Radtke, director of Louisville's Retina Vitreous Resource Center, and his colleagues have secured grants from sources such as the National Institutes of Health to perform retinal pigment epithelial research. This research continued through 1993 when collaborative efforts between local doctors and professors resulted in the recruitment of two scientists from Boston to Louisville. This lead to the filing of several patents in 1999. Since this achievement, Dr. Radtke formed Ocular Transplantation, LLC, and has advanced the clinical adaptation of this research and obtained FDA permission to perform similar transplantations in humans, primarily patients with macular degeneration and retinitis pigmentosa. These researchers were among the first groups in Louisville to receive an SBIR grant, which aids in the formation of emerging, scientifically oriented small businesses such as Ocular Transplantation.

Another researcher, Omar Buazza, PhD. – a former student of Arno Spatola, Ph.D. – works for Louisville-based Optical Dynamics, Inc. – a designer and manufacturer of equipment used to manufacture lenses for eyeglasses. Dr. Buazza holds the greatest number of patents in our report and has been a prolific inventor of special coatings for lenses, methods to apply the coatings and machines to apply the coatings. Dr. Buazza resides in Louisville. He continues to develop new products for the company

Numerous companies have formed from research activities in Louisville in recent years, but their inventions are too recent for substantial coverage in our patent study or have not yet resulted in issued patents. Among them is Assenti, LLC, comprised of Bucks for Brains faculty in Ophthalmology—Henry J. Kaplan, M.D. — and faculty in Engineering — including John Naber, Ph.D.—from the University of Louisville. Assenti will develop

and market a new biosensor platform to accurately monitor intraocular pressure without physician office visits. Another company, Regenasight, Inc., founded in 1999 by faculty from U of L – Henry J. Kaplan, M.D. and Tongalp H. Tezel, M.D. - and Columbia University, develops enzymes for treatment of diseases of the eye. J. Kevin McCurren joined the company as CEO in 2002 and in December 2003 an agreement was signed with a major biotech development fund for the development of a metallaprotease enzyme in the treatment of diseases of the eye.

Appendix I: Life Sciences Industry Sector Definitions

Biotechnology
Use of cellular and molecular processes to solve problems, cure diseases or make products relevant in human, animal or agricultural uses. Examples include gene chips, gene therapy and genetically modified foods.

Pharmaceutical/Nutraceutical
Chemically synthesized and/or naturally occurring substances used for the prevention and control of disease. Examples include combinatorial chemistry, drug delivery and nutritional supplements. Note: If the pharmaceutical involved manipulation of genes or proteins it would be classified as biotechnology.

Medical Devices
Engineered products used within or outside the body. Examples include biosensors, prosthetics/orthotics and durable medical equipment such as splints and traction devices.

Bioinformatics / Healthcare Information Systems
Bioinformatics is the science of informatics as applied to biological research. Healthcare Information Systems is the development of software applications for use in health care administration, hospital management, physician practice management, health insurance, etc.

Services
Scientific-related services for life science companies. Examples include contract research, lab services, pre-clinical services, clinical trials and a variety of manufacturing related services.

Life Science Logistics
Transportation, storage and distribution of products and devices associated with life sciences, especially with regard to substances or devices that are highly sensitive to temperature, humidity, time and motion.

Dr. Arno Spatola

Dr. Arno Spatola's journey from upstate New York to Louisville was marked by excellent training, hard work, academic achievement and diverse experiences. Born in a family with rich Italian heritage, he learned both the English and Italian languages and developed interests in science, music, culture and politics. He began his academic endeavors at Cornell University, and received an A.B. degree with a major in Chemistry and a minor in Political Science. His exceptional performance resulted in fellowships from the University of Michigan, where he received an M.S. and Ph.D while studying with Professor Daniel T. Longone. His postdoctoral research in peptide synthesis and activity was performed at the University of Arizona, which was the laboratory of noted chemist Victor J. Hruby. Thereafter, he was recruited by the University of Louisville's Department of Chemistry to initiate a peptide synthesis research program. This journey, full of achievement set the stage for a plethora of future accomplishments.

Dr. Spatola's research interests and academic career flourished. He served as a visiting professor at the University of Padova, Italy with the renowned organic chemist, Claudio Toniolo; he originated the "psi-bracket" pseudopeptide nomenclature; and was a pioneer in many areas of research. As an outgrowth of his research, Dr. Spatola founded Peptides International, Inc. in 1983, which became the first Kentucky company to receive a NSF/SBIR grant. Additionally, he, along with colleagues from the Belknap School of Medicine, founded the Institute for Molecular Diversity and Drug Design (IMD3). The annual IMD3 Symposium has quickly become a success as it attracts nationally and internationally recognized speakers and participants. In April 2003, Dr. Spatola's work was recognized at the University of Louisville when he was presented with the President's Award for Outstanding Scholarship, Research and Creativity.

Along with Dr. Spatola's successful career, he was also a family man with many interests. He was married in 1982 overlooking the snowy landscapes of St. Moritz, Switzerland to a woman by the name of Jacqulyn "Jackie" Browning "who would prove to be a superb complement for his Herculean energy and interests." Seven years later, their daughter, Kimberly Elysia was born and Dr. Spatola often referred to her as his "greatest synthesis." Dr. Spatola was said to have enjoyed tail-gating at U of L sporting events, political arguments, gourmet dinners, wine tastings, pizza, travel and Saturday morning jogs with friends.

Active Ankle Systems, Inc.

Based in Louisville, **Active Ankle Systems, Inc.** serves the medical, retail and sports team markets. It was formed in 1989 by a group of venture investors to acquire the Active Ankle product and its respective patents from the original inventor. The company is currently managed by President and CEO Glen Snow, Chief Financial Officer Diane Lilly and Chief Operating Officer Scott Morton. Its mission is to develop and market high-function, high-value sports medicine products to a variety of customers to help them return to and maintain healthy, active lifestyles.

Active Ankle's products include multiple ankle supports for a variety of conditions from post-injury to preventative uses. The innovative, patented design was a revolution in the marketplace when first designed. The product line continues to remain on the cutting-edge in the field and is a leader in its product category. Additionally, the company has developed a unique, patented device for the foot and ankle to assist in the treatment of plantar fasciitis, which affords the user a comfortable solution to alternative products. Active Ankle Systems, Inc. currently holds more than 15 United States and foreign patents covering its entire product line.

Novera

Novera is a Louisville-based life science company that plans to revolutionize wound healing with a patent-pending method of delivering intracellular energy. The company is entering a $7 billion-a-year market with immediate product development focusing on both a cosmeceutical and a prescription drug product. To date, the management team, which consists of Chief Executive Officer Patrick Migliore, Chief Science Officer William Ehringer and Vice President of Research Sufan Chien, have met several product development and financial milestones that are pertinent to the future success of the company.

Progress to-date has been supported by founder contributions, grants and awards, which included the $100,000 Vogt Invention and Innovation Fund Award in 2003. These financial milestones have allowed Novera's talented management team, scientists and researchers to develop their core technology while planning for market introduction. It is expected that the company's drug formula will be finalized by mid-2004 and that preclinical trials will be concluded by early 2005. Novera is currently seeking seed round investing in the amount of $250,000 to optimize product formulations and introduce the first product, Percura-Derm, to market.

Novera

A Word from Middleton Reutlinger

The attorneys and staff of Middleton Reutlinger are pleased to share with our community this report on health-related patents filed by numerous researchers in the Greater Louisville area.

Middleton Reutlinger is celebrating this year its 150th anniversary as a Kentucky law firm. Over these years, the firm has assisted clients of all sizes on legal issues. Our intellectual property practice counsels entrepreneurs and inventors in Louisville, throughout the country, and abroad. In 18 months, our firm issued 119 patents for our clients. It has always been our experience that the success of an invention has much to do with the steps the inventor took to patent their product, device, or method. With the turning of each year, we have witnessed the positive impact patents issued in an area of health have made and continue to make on this region we call home.

It has been a privilege to sponsor this report. The results have given Middleton Reutlinger a new perspective on the rapidly growing health industry in our region and on the inventors and entrepreneurs that keep greater Louisville ahead of other regions in our country. The success of any inventor or entrepreneur begins with an idea, a plan, and a solid support network. We look forward to supporting our clients and assisting them in keeping Louisville on the forefront in the health-related patent arena.

As a proud sponsor of this report, we hope you also will find it informative and beneficial. We welcome your thoughts and comments and hope you will join us in recognizing and supporting the significant role inventors and entrepreneurs play in both our professional and personal lives.

Sincerely,

Charles G. Middleton III
Managing Partner,
Middleton Reutlinger

HealthEnterprisesNetwork | Louisville

A Greater Louisville Inc. Affiliate

Fostering the Growth of the Region's Health-Related Economy

614 West Main Street • Louisville, Kentucky 40202

502.625.0059 • Fax: 502.625.0010 • www.HealthEnterprisesNetwork.com