Innovate4Health

The Power of Intellectual Property and Innovation in Solving Global Health Challenges

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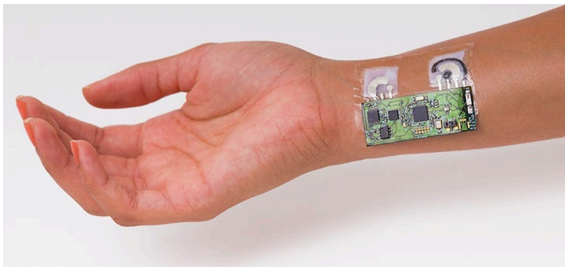

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The Power of Intellectual Property and Innovation in Solving Global Health Challenges

Many of the world's biggest challenges are health challenges. The good news is that, more than ever, people are meeting these challenges with innovative solutions.

While we still face great difficulties, people all over the world live better than ever before thanks to innovation. New medicines prevent or alleviate disease. New devices diagnose problems, repair bodies, and overcome physical challenges. Still other inventions keep vaccines and medicines fresh and effective or ensure their authenticity. New business models help innovation to happen and ensure that it reaches those who need it.

Many of these innovations are secured by intellectual property (IP) rights, which support the ability of innovators to invent and bring solutions to market. Property rights, particularly IP rights, foster the freedom of many hands and minds to work on challenging problems. They put decisions in the hands of those closest to problems—innovators with knowledge of potential solutions and caregivers and consumers who understand their own needs best. They fund individual careers and industries dedicated to solving health problems, as well as the businesses that get these solutions to individuals.

With just a bit of reflection, it becomes clear that innovation and the property rights that secure it are key to meeting global health challenges. Sometimes, however, the blinding light of necessity makes it hard to see this fact. When people are in need, it's all too easy to grow impatient with the rights of innovators. When that happens, innovators get treated as an obstacle.

We think that better public policy would result from better understanding of how innovation can meet global health challenges. Our organizations, the Information Technology and Innovation Foundation (ITIF), the University of Akron School of Law, and the Geneva Network have teamed up to tell the exciting story of how innovation is making the world healthier.

Our Innovate4Health project profiles 26 case studies covering five themes:

- Removing practical barriers to accessing treatments;
- Simplifying treatments and diagnostics to make it easier for patients to access and use them;
- Increasing efficacy and removing the detrimental side effects of existing therapies;
- Making personalized medicine accessible to more patients; and
- Reducing the global burden of non-communicable diseases as life expectancy increases.

Collectively the case studies describe how entrepreneurs are creating IP-enabled life-sciences innovations that are helping to tackle some of the world's toughest health challenges.

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Chapter 1: Introduction/Executive Summary

People face healthcare challenges all around the world, and these challenges can be especially severe in less-wealthy countries. Fortunately, healthcare innovation also happens everywhere, even in areas with limited resources. While there's a global understanding that healthcare innovation is crucial to surmounting these challenges, the remarkable efforts happening on the ground often go unnoticed. Discussions about innovation tend to focus on research in wealthy nations, overlooking the grassroots solutions emerging in less-wealthy regions.

This volume aims to highlight the brilliance and dedication of innovators in these areas, showcasing 26 original case studies that demonstrate how local and international actors collaborate to tackle healthcare challenges. By emphasizing innovation in less-wealthy countries, we reveal the powerful grassroots initiatives that occur closer to the point of care.

Innovation happens close to home.

Our research uncovered a wealth of inspiring stories about entrepreneurs and communities developing solutions tailored to their unique challenges. The findings underscore a vital lesson: those who experience health issues firsthand are often the most adept at identifying and solving them. Their deeply personal understanding leads to inventive approaches that can address even the most-pressing health concerns.

These case studies illustrate a hopeful narrative about the power of local innovation to improve health outcomes. Despite limited resources, people have shown remarkable inventiveness and determination. By creating supportive policies and environments, we can augment these efforts, recognizing that those closest to the challenges are often best positioned to craft effective solutions.

This collection serves as a tribute to the ingenuity of those working tirelessly to improve health in their communities, offering a fresh perspective on global health challenges and the innovative spirit that drives change in the face of adversity.

While these categories represent a broad range of difficulties in the provision of medicine, they nevertheless have one thing in common—the brilliant minds in the middle of things, working tirelessly to devise solutions that will save their friends, family, and neighbors from suffering.

Solutions depend on innovation.

Discussions of healthcare policy often revolve around the practical need to contain costs balanced against the need to fund expensive research and development (R&D) to develop innovative new treatments. However, this dichotomy overlooks three realities: First, innovation is often the best way to contain costs. Second, not all innovation is costly. And third, innovation happens everywhere, and effective, lower cost innovation often happens in emerging economies.

Economics illustrates just how fundamentally innovation can impact human lives. Innovators produce efficiencies that allow us to overcome scarcity and do more with the resources they have available. Paul

Samuelson explained in his introductory economics textbook that "in the world as it is, children learn that 'both' is not an admissible answer to a choice of 'which one?'"

Innovation helps defeat the iron law of scarcity. It enables people to do more things with fewer resources, repurpose traditional materials for new uses, and generate entirely new products and industries. In turn, it drives increased output, creates employment opportunities, raises wages, stimulates economic growth, and expands consumer choice. Through innovation, society gains access to previously unimaginable possibilities and capabilities. The role of innovation in driving both economic and social progress is difficult to overstate.

The need for innovation also grows ever greater as resources grow scarcer.

Medicine must reach people where they are.

One of the greatest challenges facing healthcare is simple availability. Over and over, innovators must address the lack of trained professionals, transportation, and other necessary infrastructure.

For example, infertility affects approximately 48 million couples and 186 million individuals worldwide, with about 75 percent lacking adequate access to treatment due to financial and infrastructural barriers.[1] This is especially true in low- and middle-income countries.

Argentinian startup Selectivity Life is addressing this challenge through its patented biomimetic membrane technology for sperm selection, which allows for simplified fertility treatments that can be performed in a gynecologist's office rather than requiring expensive laboratory procedures. Under CEO Jonathan Gubspun's leadership, the company has increased fertility treatment access for over 50 million couples and single mothers, raised $560,000 in funding, and expanded its innovations to include a home intrauterine insemination system.

Selectivity's work demonstrates how medical innovations can help make fertility treatments more readily available to patients around the world. While many people simply cannot get the treatments they need, medical innovations can bridge that gap and ensure that everyone has medicine.

Treatments need to be practicable to be possible.

Even when people can obtain the equipment and medicines necessary for treatments, those treatments are often too difficult to use effectively. Complicated medication regimes, sophisticated equipment, and opaque methods of use pose substantial risks to patients, especially in regions with particularly low doctor-patient ratios.

Medication non-adherence is a significant global health issue, with patients in developed nations taking their medications properly only about half the time. This failure of compliance leads to reduced drug efficacy, increased hospitalization rates, and antimicrobial resistance.[2]

To address this, Dr. Wedyan Babatain at King Abdullah University of Science and Technology (KAUST) is addressing the challenge through her patented wearable medical device technology, which uses flexible graphene to create comfortable, skin-conforming devices that can monitor, diagnose, and automatically administer medications. This innovation is particularly significant because it can be manufactured using accessible techniques such as 3D printing, making it viable for low-resource settings, where medication non-adherence is a particularly high risk.

Especially with KAUST's robust technology-sharing programs, Dr. Babatain's invention represents how innovations can make medical treatments more easily usable by anyone and everyone.

Even modern medicines leave room for improvement.

Medical treatments are often less effective than we would like, as well. While the days of humors and bloodletting are gone, many modern therapies are often just as brutal for the patients who rely on them.

Traditional cancer treatments like chemotherapy and radiotherapy come with severe side effects, damaging healthy cells alongside cancerous ones—from organ toxicity and hair loss to bone marrow suppression and radiation sickness.[3] Too often, cancer treatments are a simple matter of hoping that the cure is less dangerous than the disease.

Chilean startup Andes Biotechnologies offers a promising alternative through its drug Andes-1537, which uses "antisense" technology to precisely target cancerous cells by their unique genetic sequences while leaving healthy cells unaffected. This more-targeted approach could revolutionize cancer treatment by eliminating the harsh side effects of conventional therapies, and potentially treat all forms of cancer.

Thanks to patent protections that helped secure $10 million in funding, the company has advanced through FDA clinical trials, bringing this gentler and more-effective treatment option closer to patients who currently face limited choices between aggressive therapies or none at all. Bridging that gap illustrates just how important it is to ensure that we continue to improve on existing treatments, in terms of both greater efficacy and lesser side effects.

Personalized medicine is an opportunity to more effectively meet a patient's needs.

Logistical challenges to healthcare are often met with simple numbers, especially in a global setting—if we mass-produce enough pills, surely we can medicate the whole world. However, good medicine is not one-size-fits-all, and it is dangerous to assume so. Modern technology provides an invaluable opportunity to tailor treatments to individual patients.

Colombian company Smartbone, led by engineer Catalina Isaza, has revolutionized craniofacial implant treatment by developing a patented ceramic-polymer compound that can be customized to each patient's unique needs. Unlike traditional titanium implants, these personalized prosthetics not only cost one-third less than imported options but also better resemble natural bone, promote bone growth, and can be precisely shaped to restore both function and aesthetics for each individual patient.

This personalization is particularly valuable for treating the diverse range of craniofacial injuries and congenital defects that affect millions worldwide, from accident victims to children born with conditions like cleft palate. Through a strategic partnership with distributor Innmetec, Smartbone has already provided customized treatment to hundreds of patients in Colombia and is expanding across Latin America, demonstrating how individualized medical solutions can improve patient outcomes while reducing costs and wait times.

The global disease burden is shifting toward non-communicable diseases.

As life expectancy increases worldwide and communicable diseases are gradually eliminated, humans begin to live long enough to suffer from a host of non-communicable diseases that were previously rarer. As healthcare

burdens shift to reflect this change, it becomes increasingly important to enable healthcare systems to better handle this growing non-communicable disease burden.

Leukemia, which affected nearly 475,000 new patients globally in 2020 and caused over 311,000 deaths, presents a significant healthcare challenge that is further complicated by widespread drug shortages.[4] This is particularly worrisome in countries like Saudi Arabia, where all major oncological institutions report treatment disruptions affecting patient care.

Saudi Arabian researcher Asma Saeed Al-Amoodi has developed a promising solution through her patented innovations in blood stem cell treatments at KAUST. Her breakthrough involves improving the efficacy of bone marrow transplants by enhancing blood stem cells' ability to target and graft to affected areas, potentially offering a more-reliable treatment option for leukemia patients who currently face uncertain outcomes even with successful transplants. Al-Amoodi's innovations are attracting the funding and recognition needed to develop these treatments further, demonstrating how healthcare innovation can help advance solutions for complex noncommunicable diseases.

Global pandemics such as COVID-19 present unique challenges to healthcare.

The coronavirus presented a wholly unanticipated global challenge in the last several years, and many regions struggled to manage the pandemic. Fortunately, many local innovators found novel solutions to combat a novel disease.

For example, while traditional medicines are often dismissed as unscientific, they are vastly more readily available to rural populations than many blockbuster drugs, which can be lifesaving during a global pandemic. Traditional medicines also have historically informed many modern medical treatments, with two-fifths of modern pharmaceuticals having roots in traditional practices.[5]

Herbanext Laboratories, a Filipino drug manufacturer founded in 2001, exemplifies how traditional medicine can be modernized through scientific research. The company has successfully standardized herbal extracts for medicinal use, most notably developing a refined medicine from the tawa-tawa herb that has proven effective against both dengue fever and COVID-19 symptoms.

The company's work demonstrates how investment in pharmaceutical R&D can improve traditional medicines through clinical trials and standardization, while simultaneously promoting biodiversity conservation and economic development in regions rich in natural resources such as the Philippines. This grass-roots approach to healthcare is especially important in handling COVID-19 and other such diseases that severely test supply chains, resources, and international collaboration.

Healthcare faces many problems, but human ingenuity is inexhaustible.

We have found that while healthcare challenges vary widely, there are nevertheless patterns that emerge. We have grouped these case studies based on what challenges people face, both to illustrate how many different solutions people devise and to emphasize the common ground that humanity shares in its struggle for physical wellbeing.

Among the diverse challenges addressed here are:

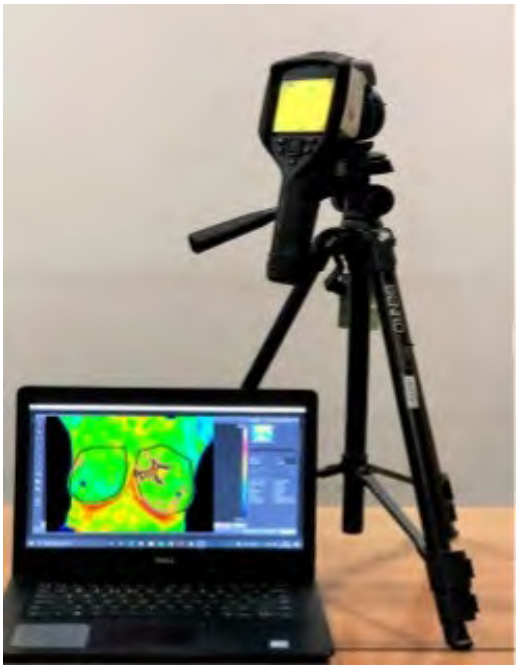
- Removing practical barriers to accessing treatments;
- Simplifying treatments and diagnostics to make it easier for patients to access and use them;
- Increasing efficacy and removing the detrimental side effects of existing therapies;
- Making personalized medicine accessible to more patients; and
- Reducing the global burden of non-communicable diseases as life expectancy increases.

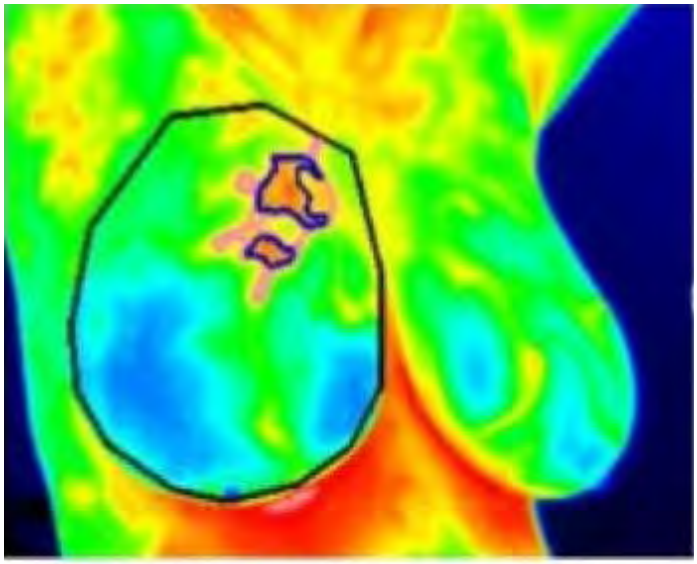
We hope that this report will contribute to a better understanding of the importance of IP-driven innovation in meeting global health challenges.

Chapter 2: Challenge: Removing Practical Barriers to Accessing Treatments

NIRAMAI Thermalytix: Transforming Early Breast Cancer Detection in India

By Natalie Khoo





Thermalytix Image with biopsy proven T1 lesion of size 1.7cm X 1.4 cm

Breast cancer looms as a silent threat to millions of women globally, affecting approximately one woman every 14 seconds, somewhere across the world.[6] With the increasing incidence of breast cancer, the global cancer burden is only likely to increase, especially in low-income countries such as India. While early breast cancer diagnosis through mammography screening programs is crucial to reducing the breast cancer burden, women in India are 50 percent less likely to be diagnosed early with breast cancer than women in high-income countries.[7] This is underscored by India's three-year breast cancer survival rate of 68 percent, as compared to the global average of 84 percent.[8]

Amidst India's breast cancer crisis emerges NIRAMAI Thermalytix—a novel artificial intelligence (AI)-based medical device that detects breast cancer at a much-earlier stage by utilizing patented machine learning algorithms to analyze thermal imaging data (Patent numbers: US 9898817, US10307141, US10055542, US9622698).[9] NIRAMAI, which stands for "Non-Invasive Risk Assessment with Machine Intelligence," is at the forefront of highlighting the transformative role that IP can play in the healthcare innovation field in low-income countries with its patented technology called Thermalytix©. To date, NIRAMAI has been granted 33

patents, including 11 in the United States and others across Europe, India, Japan, and Singapore as well as Canada to ensure the company's IP is widely protected.[10]

The World Health Organization (WHO) recommends a doctor-patient ratio of at least 1:1000—one doctor per 1000 patients—to ensure adequate healthcare coverage. In India, however, this ratio is significantly lower, with only 0.74 doctors per 1,000 patients, in contrast to the top 10 GDP-ranked countries.[11] The team at NIRAMAI, under the leadership of CEO Dr Geetha Manjunath addressed this problem through an innovative approach. By offering an automated and portable cancer screening tool that can be easily operated in any clinic, even by low-skilled personnel, NIRAMAI Thermalytix demonstrates the ability to provide essential breast cancer screening services to women of all ages in resource-constrained environments where mammography screening is not feasible.[12]

Since its launch, NIRAMAI's low-cost medical device has helped more than 100,000 women across India and globally by enabling early screening for breast cancer. It is able to reduce diagnostic costs by approximately 95 percent compared to traditional screening methods.[13] Moreover, NIRAMAI Thermalytix's radiation-free approach, combined with its non-invasive and painless imaging method, also makes breast cancer screening a comfortable and pain-free experience, as opposed to traditional mammography, which can cause discomfort or pain for some individuals. Similarly, the patented technology of Thermalytix not only provides affordable, reliable, and high-precision breast cancer screening services, but also ensures timely detection, as it can detect significantly smaller tumors (≤2cm) than those that can be detected through clinical breast examination and the whole process takes only 10 to 15 minutes.[14]

NIRAMAI Thermalytix's success has attracted significant financial backing—the company has raised a total of $7 million from institutional investors in India, Japan, and Singapore, such as Dream Incubator, pi Ventures, and Ankur Capital, just to name a few.[15] The Bill & Melinda Gates Foundation and numerous others have acknowledged the value of the innovation, and awarded the inventors funding to continue research, development, and deployment of their innovation.[16] Additionally, with its U.S. Food and Drug Administration (FDA) approval in 2022, NIRAMAI became the first Indian company to receive both European Medicines Agency (EMA) and U.S. FDA clearance for a medical device used for women health, marking a significant milestone in the healthcare company's journey as it enters the lucrative US market.[17]

In addition to its application in breast cancer screening, NIRAMAI has also employed its technology to respond to the COVID-19 outbreak by introducing "FeverTest." This device combined NIRAMAI's most-awarded novel AI solution, Thermalytix, with a thermal camera to detect elevated temperature (fever).[18] This further highlights the pivotal role of IP protection, as NIRAMAI's patented technology was able to quickly adapt its technology to an urgent health crisis, amplifying community screening and complementing India's national response to combating COVID-19.

Intellectual property rights have played a significant role in bringing NIRAMAI Thermalytix to market. According to CEO Manjunath, "patenting has become a way of life," emphasizing the importance of protecting innovative ideas.[19] She advocates for startups to leverage government initiatives such as fast-tracking, reimbursement of application fees (with caveats), filing under the Patent Cooperation Treaty (PCT), thorough scrutiny of Non-Disclosure Agreements (NDAs), and access to research grants.[20] This underscores the significant role of patents in enhancing the value of a startup and supporting innovative health solutions.

NIRAMAI Thermalytix's success has demonstrated the great potential for improving early breast cancer detection in low-income countries such as India. This advancement in breast cancer screening technology is crucial, especially in low-resource settings where organized mammography screening is not feasible due to factors such as affordability, limited healthcare access in rural and remote areas, infrastructure constraints, and shortage of healthcare providers.[21] NIRAMAI Thermalytix has shown promise in bridging the gap in breast cancer diagnosis and ultimately saving lives. Its technology and the IP embedded within represent one important piece of the larger policy puzzle that affects healthcare outcomes in low-income countries.

From Plants to Patients: How Intellectual Property Propelled La-Africa Soother's Natural Approach for Pain Relief

By Natalie Khoo

It's no secret that sports and physical activity offer a myriad of health benefits for both physical and mental well-being. From shielding against heart attacks to alleviating stress, the positive effects of engaging in physical activity cannot be overstated. However, there is also an inherent risk of musculoskeletal injuries, particularly joint injuries and post-traumatic arthritis, a condition that causes stiffness and pain around joints.[22] This risk is particularly pronounced among athletes, sports, and fitness enthusiasts, who subject their joints to significant wear and tear compared to the average individual.

Post-traumatic arthritis impacts more than 5 million people every year, accounting for approximately 12 percent of all osteoarthritis cases.[23] This condition occurs most commonly in the knees, hips, lower back, the neck, small joints of the fingers, and the base of the thumb. Despite rapid advances in biomedical engineering, addressing bone and cartilage repair in joints after an injury remains a great challenge in the field of regenerative medicine. This challenge has always been of particular interest for Professor Keolebogile Shirley Motaung, Director of Technology Transfer and Innovation at Durban University of Technology in South Africa.[24] Witnessing her mother's struggle with the chronic pain associated with osteoarthritis and the weaknesses of the South Africa healthcare system to provide adequate care, Professor Motaung was determined to find a way to alleviate the suffering that patients with musculoskeletal injuries have to endure.

In 2015, Professor Motaung founded Global Health Biotech (Pty) Ltd., a spin-off company based in South Africa.[25] Drawing upon South Africa's rich biodiversity and long history of indigenous communities use of

medicinal plants to treat various kinds of illnesses, the team at Global Health Biotech Pty Ltd. created La-Africa Soother—an innovative plant-based anti-inflammatory cream made from African teak, a tree of woodlands and savannahs, and the pineapple lily, a short, showy flower.[26] These plants contain compounds that can activate body cells, promote bone formation, and facilitate wound healing. When combined with stem cells, they guide the growth of new tissues, in a process known as "scaffolding."

In low- and middle-income communities all across the world, financial and structural barriers often prohibit individuals from assessing essential bone and cartilage treatments such as bone morphogenic proteins, primarily due to their high costs, and South Africa is no exception.[27] La-Africa Soother emerges as a low-cost, safe, and non-invasive alternative treatment for musculoskeletal injuries.[28] Unlike other creams targeting muscle aches and joint pains, La-Africa Soother is the first product of its kind aimed at preventative care.[29] By applying La-Africa Soother before and after engaging in physical activity, it can reduce the likelihood of anticipated muscle aches. Since this innovative invention is a plant-based anti-inflammatory cream, it also has restorative abilities which are unique to the market. Due to its plant-derived medicinal composition, La-Africa Soother is able to promote the development of collagen type II, the main structural component of the cartilage tissue in joints.[30]

Intellectual property rights have played an instrumental role to the success of Global Health Biotech (Pty) Ltd. According to CEO Motaung, "From the outset, it was clear that intellectual property would be central to Global Health Biotech's future," highlighting the foundational importance of safeguarding innovations through patents and other forms of intellectual property to drive innovation forward.[31] To date, Global Health Biotech (Pty) Ltd. has secured patents from the European Patent Office (80298/Munich, Germany: 18836901.3-112) and South Africa: (2017/08330).[32] As a company dedicated to providing high-quality and affordable plant-based products, La-Africa Soother has helped individuals suffering from chronic joint and muscle pain associated with musculoskeletal injuries in areas with inadequate access to essential medical products. Global Health Biotech (Pty) Ltd. has demonstrated the importance of effective intellectual property rights and trademark protection in the development and commercialization of its own brand and services.[33]

Additionally, intellectual property rights empower innovators to increase their impact by partnering with local research universities. As Professor Motaung highlighted, "The fact that the Durban University of Technology covered our patent fees, and that I have been able to license it at a much lower cost, has really assisted our business."[34] Building on this success, Professor Motaung is currently working to include intellectual property training in the curricula for the university's science degrees.[35] By doing so, she aims to cultivate a new generation of innovators and business leaders, equipping them with the tools to bring their ideas to market successfully. In addition, she advocates for universities to not just hold onto their intellectual property rights but to actively "license those patented technologies," ensuring that valuable innovations are not left dormant, but are instead utilized to benefit society and contribute to economic growth.[36]

Since the launch of La-Africa Soother, Global Health Biotech (Pty) Ltd. under the leadership of Professor Motaung, has garnered numerous awards, including the Strategic African Women in Leadership (SAWIL) Trailblazers Award for 2022/2023 and was honored as top innovator in the Chancellor's Awards under Impactful: Collaborative Entrepreneurial Project between Technology Transfer & Innovation—to name a few.[37] Also, the World Intellectual Property Organization (WIPO) has acknowledged the value of the innovation, as it was featured in the WIPO Development and Intellectual Property Committee project

on *Increasing the Role of Women in Innovation and Entrepreneurship, Encouraging Women in Developing Countries to Use the Intellectual Property System.*[38]

La-Africa Soother's story has illustrated how intellectual property can transform innovative ideas into life-changing solutions in the healthcare field. It is a testament to the important role intellectual property and collaborative partnership play in driving innovation forward especially in low-income countries.

Herbanext Laboratories Turns Traditional Medicine Into Modern Healthcare

By Douglas Park

Though sometimes dismissed as unscientific, traditional medicine can offer substantial therapeutic value. As noted by the WHO, however, traditional medicines can be dangerous in many contexts because these medicines lack the research and testing necessary to prove that they are both safe and effective. Traditional medicines can also provide a foundation for further drug development, especially for other diseases and conditions, but incentives to invest in exploring such new uses are lacking. Herbanext Laboratories, a Filipino drug manufacturer, leads the charge in not only testing drugs derived from native plant life but also in discovering and developing invaluable new applications for them.[39]

Traditional medicine typically lacks much of the regulatory oversight that applies to other drugs to ensure their safety and efficacy, but centuries of experience also can provide evidence of safety and efficacy. Rather than simply dismissing these practices, many pharmacologists have discovered that they instead can leverage ancient and indigenous medicinal practices to inform modern medicine.

For example, the use of vaccines is a direct descendant of variolation, a practice of intentionally exposing patients to smallpox that was used to treat smallpox for thousands of years.[40] The principle of inoculation has been foundational to medicine almost as long as humans have practiced healthcare. Fully two-fifths of modern pharmaceuticals were developed from traditional medicine in some capacity, from aspirin's Sumerian roots to refining opium into morphine.[41] It is therefore vital that groups like Herbanext work to refine these treatments to ensure their safety and efficacy.

Herbanext Laboratories began in 2001 with cultivation and processing of medicinal reishi mushrooms. They shifted to extraction and spray-drying in 2011 with funding from the Philippines' Department of Science and Technology (DOST), soon after becoming one of the largest suppliers of herbal ingredients in the country. Herbanext proudly claims the title of the first Filipino company to standardize the production of herbal extracts for medicinal use, a very important step in ensuring that patients receive safe and effective doses of these traditional medicines and that they do not contain dangerous impurities.

In 2019, Herbanext announced the availability of a refined and concentrated medicine made from the *tawa-tawa* herb, also known as *Euphorbia hirta*.[42] Tea made from the *tawa-tawa* herb has been used for centuries to fight dengue, and recent research indicates that the herb has antiviral and pro-platelet properties. After the Filipino Department of Health announced a national dengue epidemic, Herbanext created a *tawa-tawa*-based

herbal supplement to be administered in precisely modulated capsule form. Herbanext notes that this formulation offers a much more targeted and effective treatment than the traditional but inexact method of brewing tea.

Furthermore, when the COVID-19 pandemic broke out in 2020, it turned out that Herbanext's *tawa-tawa* extracts could treat more than just dengue. In March of 2021, the University of the Philippines Visayas, Corazon Locsin Montelibano Memorial Regional Hospital, Philippine Red Cross of Manila, Quezon Institute, and DOST began clinical trials to test Herbanext's *tawa-tawa* medicine as an adjunctive treatment for COVID symptoms.[43]

In late 2021, trials confirmed the use of *tawa-tawa* to treat COVID symptoms, and DOST began additional research and testing to meet Filipino FDA standards for "effective against COVID" labeling.[44] DOST has stated that these additional treatments were invaluable for many Filipino citizens, for whom more popular drugs like remdesivir or tocilizumab were both hard to find and prohibitively expensive. As a result, less-wealthy patients have often relied heavily on the accessibility and affordability of traditional medicine such as Herbanext's products, especially after the 2004 Proclamation No. 698 that made proven traditional medicine available through the national healthcare system.

None of this would have been possible without Herbanext's dozens of patents, of course.[45] While traditional medicine itself is generally unpatentable, the improvements that Herbanext's researchers have made present substantial advancements in the efficacy of these treatments. The clinical trials necessary to ensure the safety and efficacy of these drugs are expensive, however, and it is only with the funding enabled by patent protections that Herbanext has been able to prove the value of its products and make them available to people across the Philippines.

This process also illustrates how patents promote iterative innovation. If companies like Herbanext were unable to secure patents on incremental improvements like their herbal extractions, then they would have neither the means nor incentive to make those improvements. It is because of the patents that Herbanext and others can turn inconsistent and unregulated herbal teas into tested and proven medicines that can save lives.

These innovations also foster greater cultivation of native biodiversity, which provides both socioeconomic and ecological benefits. The Philippines has 32,000 species of terrestrial flora and fauna and 10,000 aquatic species, and yet the nation derives less annual value from its biodiversity than it does from exploitative industries like fishing, mining, and forestry.[46]

Philip Cruz, founder of Herbanext Laboratories, says that "Biodiversity is [the Philippines'] most underutilized economic resource," and that the cultivation necessary to fully leverage that resource will also benefit conservation efforts. Instead of conventional monoculture farming, diversification will strengthen the indigenous ecosystem and provide a reliably broad portfolio of renewable natural resources.

Modernization of traditional agriculture and medicine provides comprehensive socioeconomic benefits, but it is only possible through robust intellectual property protections. By maintaining a patent system consistent with international standards, the Philippines is well on its way to becoming one of the largest innovation economies in the world.

Selectivity Life, Harnessing Innovation to Expand Access to Fertility Treatments

By Natalie Khoo

Infertility, commonly defined as the inability to achieve a pregnancy after 12 months or more of regular, unprotected sexual intercourse, is a pressing global health issue.[47] Estimates suggest that infertility impacts 48 million couples and 186 million individuals of reproductive age worldwide, often with devastating consequences.[48] According to Dr. Tedros Adhanom Ghebreyesus, Director-General at the World Health Organization (WHO), this disease of the male and female reproductive system "does not discriminate" and approximately one in six people have experienced infertility at some stage of their lives.[49]

Beyond responding to declining birth rates, addressing infertility is crucial for upholding individuals' sexual and reproductive health and rights (SRHR). However, infertility policies and services in many countries fall short of adequately addressing this pervasive issue. This shortfall can often be attributed to restrictions on individuals' ability to access essential services they need, such as assisted reproductive technologies (ART). The global demand for ART solutions to infertility continues to grow, with a market size valued at $25.7 billion. In the United States alone, approximately 238,126 patients had 413,776 ART cycles in 2021, which accounted for 2.3 percent of all infants born in the country that year.[50]

While there have been significant advancements in fertility treatments, such as *in vitro* fertilization (IVF), which have revolutionized the notion of human reproductive potential, access to these innovative scientific technologies is still largely unavailable, inaccessible, and unaffordable to many, particularly in low and middle-income countries.

Currently, 75 percent of individuals affected by infertility worldwide lack adequate access to treatment due to financial barriers, a shortage of trained personnel, or simply a lack of necessary equipment and infrastructure.[51] As fertility treatments are predominantly funded out-of-pocket, it often places a significant financial burden on individuals and families residing in low- and middle-income countries. Reports estimate that a single IVF cycle can range from $15,000 to $30,000, underscoring the enormous financial strain associated with seeking care

and the persistent challenge of ensuring equal and equitable access to fertility care, particularly in low- and middle-income countries.[52]

The team at Selectivity Life, a medical startup based in Argentina, has tackled this global health challenge head-on by redefining what accessible, affordable, and most importantly, inclusive innovation in fertility care looks like.[53] By leveraging the company's patented technology (Patent numbers: AU2024201489, CA3053877, US20200032199, WO2018154169)—a biomimetic membrane for sperm selection—the innovators at Selectivity Life created an innovative sperm selection device that shifts traditional paradigms of laboratory-based fertility treatments to a more convenient and patient-centered approach.[54]

Unlike current infertility treatments, Selectivity Life's innovative medical solution is non-invasive and allows procedures to be conducted right in the comfort of an obstetrician gynecologist's office, ultimately simplifying the journey toward conception, making the process more accessible and less daunting for those involved. The patented technology enables efficient and effective sperm selection by mimicking the natural physiological barriers sperm must navigate to fertilize an egg, thus ensuring DNA fragmentation is kept at a minimum, increasing the likelihood of successful conception.[55] This approach not only improves the quality of sperm used, but also eliminates the need for costly and complex medical procedures and equipment, reducing the financial strain and emotional stress patients must endure, especially in resource-constrained environments.[56]

Selectivity Life has made a tremendous impact in the current infertility treatment landscape. Under the leadership of founder and CEO, Jonathan Gubspun, the company has successfully increased access to fertility treatments for over 50 million couples and single mothers who previously faced substantial barriers to accessing ART.[57] Similarly, the startup's success has attracted significant financial backing from Córdoba Innovation and Entrepreneurship Agency and CITES, an accelerator and technology-based business incubator of early scientific-technological projects.[58] Notably, the company has managed to raise a total of $560,000 to fuel further development and expansion of Selectivity Life's medical innovation portfolio.[59] The value of the innovation has also been recognized on a global scale as Selectivity Life was one of the three startups from Argentina that were chosen as the finalists for the Entrepreneurship World Cup in 2023, marking a significant milestone for the health startup.[60]

The role of intellectual property cannot be understated, especially in this space. For startups like Selectivity Life, securing patents is crucial in ensuring they maintain a competitive edge in the market. Moreover, it provides them with the leverage needed to negotiate partnerships and funding, which are crucial for scaling operations and expanding their impact on global health challenges.

The profound impact of Selectivity Life's intellectual property is evident in the expansion of their product range. Building on the success of the patented technology in the sperm selection device, the team created a home intrauterine insemination (IUI) system, a single device that allows IUI's to be conducted in the comfort of one's home.[61] Designed for simple and easy use, this user-friendly solution offers a significant improvement in the quality of life for individuals struggling with infertility.

As fertility management strategies are deeply personal journeys that vary widely from one individual to another, Selectivity Life offers a range of options tailored to meet the diverse needs and circumstances of those aspiring to start or grow their families, as the debilitating nature of infertility not only affects physical health but also inflicts significant emotional and mental stress. The success of the team at Selectivity Life has not only demonstrated the critical role of innovation and intellectual property in addressing global health challenges but also serves as a beacon of hope for millions of individuals suffering from infertility.

MScan Uganda is Advancing Maternal Healthcare and Driving Social Impact Through Its Innovative Portable Ultrasound Technology

By Natalie Khoo

Improving maternal mortality was one of the 17 Sustainable Development Goals (SDGs) adopted at the 2015 Sustainable Development Summit. Specifically, SDG 3.1 aims to reduce the global maternal mortality ratio to less than 70 per 100,000 live births by 2030.[62] This underscores the urgent need for innovative maternal healthcare solutions, particularly in low and middle-income countries such as Uganda, where maternal mortality remains alarmingly high.

According to the World Health Organization, more than 800 women die every day from pregnancy-related complications—meaning that a woman dies approximately every two minutes.[63] This is particularly concerning as 95 percent of all maternal deaths occur in developing countries and are often due to preventable causes resulting from conditions such as amniotic fluid deficiencies or umbilical cord complications that could be identified and managed with timely and proper medical diagnostics.[64]

While obstetric ultrasound is an integral component of prenatal care and is a common tool used in high-income countries, it remains largely unavailable in sub-Saharan Africa. Sixty percent of women in sub-Saharan Africa go through their entire pregnancy without the benefit of a single ultrasound examination, exacerbating the disparity in maternal health outcomes between developing and developed countries.[65] Similarly, the lack of access to this vital diagnostic tool contributes to the region's high perinatal mortality rates, which are approximately 10 times higher than those in high-income countries.[66] For example, in Uganda, the stillbirth

rate is 17.8 per 1000 live births which is significantly higher than the global average of 13.9 per 1,000 live births.[67]

Recognizing the need to bridge this gap, MScan Uganda—cofounded by Dr. Ahimbisibwe Prosper, Phyllis Kyomuhendo, Menyo Innocent, and Nasasira Ivan—emerged as a pioneering initiative to address the maternal health challenges faced by pregnant mothers living in rural communities throughout Uganda.[68] Driven by the urgent need to curb the high maternal mortality rates through early detection and effective medical intervention, the team created MScan, a patented, low-cost, portable ultrasound probe that connects to a phone or laptop to provide an affordable sonogram to pregnant mothers in rural Africa (Patent numbers: UG U/2018/000008, UGP/2019/000006).[69]

This innovative device brings advanced prenatal care within reach of those who need it most. By utilizing piezoelectric crystals and digital signal processing chips to send out and receive ultrasound waves, MScan's technology has effectively miniaturized the size of a traditional ultrasound machine, reducing it from a large, bulky device to a pocket-sized probe that can easily connect to a laptop or phone preloaded with the MScan app to display the image in real time.[70] Unlike competitors such as Clarius Health and Philips Lumify, MScan's device connects via USB port 2.0 and above, making it compatible with a wide range of devices.[71] Thus, this compact and portable design allows healthcare providers in remote areas to conduct detailed ultrasound examinations with minimal resources, overcoming the infrastructure challenges often faced in these regions.

In addition, MScan's affordability is what sets it apart from other devices on the market. The cost of an MScan probe, complete with a smartphone or laptop, is around $2,500—nearly one-tenth of the price of traditional ultrasound machines, which can range from $15,000 to $20,000.[72] This significant reduction in cost makes advanced prenatal care more accessible to underserved communities, thereby bridging the gap in maternal healthcare services. Furthermore, MScan partners with private medical facilities to offer ultrasounds at an affordable rate of only $2 per session, compared to the $10 typically charged in some private hospitals. According to Dr. Ahimbisibwe, this pricing model ensures that essential diagnostic services are more accessible to mothers while also contributing to the financial sustainability of the facilities.[73]

Since its inception in 2017, MScan has made a significant impact on maternal healthcare in Uganda. To date, the initiative has performed over 3,000 ultrasound scans, detecting more than 1,500 complications.[74] Notably, 20 percent of these scans identified complications that led to timely referrals for medical and surgical interventions.[75] Besides, the team is also focused on empowering and training local health workers to use the technology effectively. This is demonstrated by the company's effort in conducting over 25 training sessions and 10 medical camps held.[76]

The company's commitment to social impact and equitable healthcare access has also made headlines on various prestigious platforms. The team's dedication was highlighted when they were featured in MIT Solve, showcased in the Africa Innovation Challenge 2.0 by Johnson & Johnson, and honored with The Builders of Africa's Future 2022 Award by the United States Africa Development Foundation.[77] They also triumphed at the TechCrunch Startup Battlefield Africa, where their innovative approach and potential for significant impact were celebrated.[78]

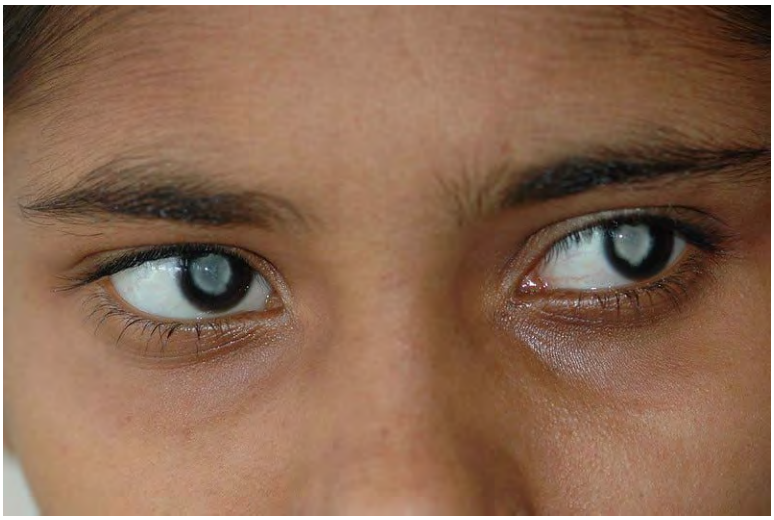
MScan's motto, "Save a Mother, Save a Life," is evident in every aspect of its work. As MScan continues to grow and innovate, its focus remains on scaling its efforts to reach more underserved communities. The team aims to expand the company's impact by increasing the number of scans performed, further training local health

workers, and enhancing the affordability and accessibility of their technology. MScan's commitment to bridging the healthcare gap in East Africa reflects a broader vision of equitable healthcare for all, making a profound difference in the lives of countless mothers and children.

Chapter 3: Challenge: Simplifying Treatments and Diagnostics to Make It Easier for Patients to Access and Use Them

Seeing Is Believing: FOODVICA's Innovative Non-Surgical Cataract Treatment

By Kristen Thompson



Imagine trying to see the outside world through a frosted window. That's what life is like for millions of individuals with cataracts, one of the leading causes of preventable blindness worldwide.[79] While cataract surgery is highly effective, the procedure itself is not always readily available. To address this issue, Mexican company Foodvica has developed a new way to treat cataracts with medication, as a cutting-edge, non-invasive option.

In Mexico, inadequate surgical and healthcare resources impose significant challenges in treating cataracts. Research suggests that a substantial portion of ophthalmologists do not have the resources necessary to perform cataract surgery.[80] Despite having approximately 5,000 ophthalmologists, Mexico struggles to address the healthcare needs of the population, with one million individuals lacking access to essential surgical procedures.[81]

This is particularly concerning for Mexico's rapidly aging population, who are experiencing an increasing incidence of cataracts with advancing age. Projections indicate that by 2020 nearly 20 percent of the population, or approximately 23 million individuals, will be over the age of 50.[82] Risk of cataract formation also includes factors such as obesity and diabetes, and Mexico has one of the highest diabetes and obesity rates in the world.[83]

In addition, a 2015 Manatt Jones study revealed that cost is the primary barrier to cataract surgery in Mexico, with the operation inaccessible to 40 percent of patients.[84] Mexico spends a good deal less of its gross domestic product (GDP) on health care than the average among other countries, leaving patients to pay almost half of their health care costs out of their own pockets. Frequently long waiting lists for surgery further stall cataract surgery.[85]

To address these challenges, Labcymo, a division of Mexican company Foodvica, has developed a non-surgical, nanotechnology-based treatment for cataracts.[86] Their formulation promises an affordable and accessible solution for patients at all stages of cataract development, potentially transforming the landscape of cataract care worldwide.

Previous attempts to develop non-surgical cataract treatments have shown little promise, requiring regular application of several large doses of medication.[87] By contrast, Labcymo's novel combination of known

therapeutic compounds have demonstrated significant potential in treating certain types of cataracts with relatively few and small doses.[88]

Labcymo's treatment also makes use of smaller particles of the active ingredient, allowing greater absorption and distribution in a patient's eye. Given that the treatment works by applying bioactive compounds to break down and decrease the buildup of proteins that cloud the eyes, Labcymo's greater permeation increases the overall effectiveness of the treatment.[89]

While Labcymo plans to offer its treatment for cataract patients around the world in the near future, it is still in the early stages of testing. Gaining regulatory approval for new medical treatments typically requires clinical trials that can take many years and hundreds of thousands or even millions of U.S. dollars.

It is not easy to attract this much investment for testing, however. Labcymo has decided to develop its cataract treatment for veterinary use first, not only to show how effective the medication is but also to secure funding for the considerably more expensive clinical trials needed for human use. Testing and other development costs for veterinary use are routinely only a fraction of those for human use.[90]

Regardless of whether testing a pharmaceutical for human use or veterinary use, however, companies would not be able to afford to invest in the intensive testing needed for regulatory approval without the protection of intellectual property rights. Patents in particular provide inventors such as Labcymo with the rights to keep others from making, using, or selling their inventions.

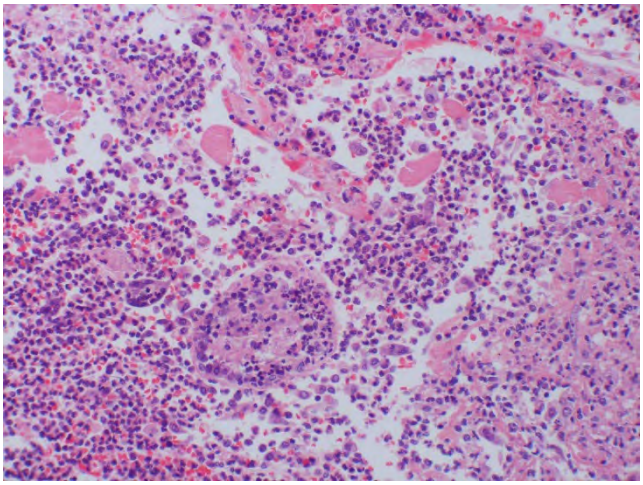
Without patent rights, by contrast, competitors might copy not only others' inventions but their investments in developing those inventions. Patents are therefore vital in protecting investments in inventive new technologies, such as testing new treatments in order to grain regulatory approval to market them.

Labcymo's commitment to developing it cataract medication is evident in its patent applications not only in Mexico but also in other countries. Labcymo has filed applications through the PCT, under which innovators can seek patent protections in multiple countries through a coordinated process.[91]

In this way, Labcymo can more easily bring its cataract medication to patients in many different countries without fear of losing the hard work, time, and money that it has put into its innovative treatment. In turn, these essential protections will enable Labcymo to continue developing its groundbreaking work into a new and more readily accessible non-surgical alternative for those who otherwise might not be able to receive treatment for their cataracts.

Wearable Respiratory Rate Monitoring Glove: A Breakthrough in Childhood Pneumonia Detection in Bangladesh

By Krishna Sankya Talluri



Pneumonia is a curable and mostly preventable lung disease, with a mortality rate of only 1 to 3 per 100,000 children in high-income countries, and generally is not perceived as a serious public health concern.[92] Pneumonia nonetheless has a disproportionate effect on children in low- and middle-income countries (LMICs) because pneumonia often goes undiagnosed and untreated until children in those countries are already severely ill.[93] In 2019 alone, pneumonia accounted for 14 percent of children's deaths globally, with most of those deaths occurring in economically weaker communities.

To address this disparity, University of Edinburgh academic Dr. Srinjoy Mitra led a multinational team to devise a convenient, versatile, and affordable device that a user can literally wear in the palm of their hand to diagnose cases of childhood pneumonia. This device could significantly improve early diagnosis and treatment in countries such as Bangladesh, where access to larger, more-expensive diagnostic and monitoring equipment is very limited.

Bangladesh is a quintessential example of an LMIC that has consistently struggled to curb the impact of pneumonia. In 2018 alone, pneumonia claimed the lives of more than 12,000 Bangladeshi children, accounting for approximately 13 percent of all mortalities among children under 5 years of age.[94]

A large part of the problem with identifying and treating children with pneumonia early enough is the lack of reliable diagnostic equipment. In LMICs like Bangladesh, health care providers must instead rely on much more subjective clinical indicators such as coughing and increased respiratory rates.[95]

These care providers often must measure a child's number of breaths per minute manually using watches, timers, or abaci.[96] Measuring respiratory rate visually demands intense focus and can be particularly challenging if the child is moving, crying, or breathing rapidly—all of which are likely in a sickly child.

To tackle this issue, Dr. Srinjoy Mitra led a dedicated team of researchers at the University of Edinburgh to develop the "Multi-Modal Portable Respiratory Rate Monitoring Device for Childhood Pneumonia Detection Device," a small and easily portable diagnostic device that can be worn as a glove.[97] This project is groundbreaking because it does not require expensive equipment such as X-rays or blood tests for diagnosis and allows doctors to treat childhood pneumonia earlier and more successfully. Dr Sadeque Reza Khan, a Bangladeshi national working in Edinburgh, is the lead author of this paper.

The rechargeable prototype of the diagnostic device comprises two primary components: simple hardware and a cloth glove. The glove has textile electrodes on the palm and fingertips and a printed circuit board on the back. The textile electrodes measure bio-impedance caused by respiration while the accelerometer monitors the patient's breathing.

The device transmits this data to a mobile app via Bluetooth, allowing healthcare professionals to assess the data remotely. The electronic components are even detachable, allowing the user to wash the glove separately or even replace it altogether. This flexibility ensures reusability and helps prevent infection.

Initial tests of the glove design done in collaboration with the University of Dhaka in Bangladesh have successfully demonstrated high accuracy as well as capacity, with battery life allowing uses up to 60 to 70 times a day. The research team next plans to expand the device's capabilities to other diagnostic methods such as electrocardiograms.

Dr. Mitra and Dr. Khan do not yet have published patents on this device, but it is likely that the possibility of patent rights was essential to securing funding for the project. The University of Edinburgh, this project's primary sponsor and a staunch supporter of knowledge sharing and licensing of IP in less wealthy nations, also stresses the importance of commercializing and distributing new health-related technologies such as Dr. Mitra's diagnostic glove.[98]

Though human wellbeing is an essential motivation, investors like the University of Edinburgh recognize the need to secure substantial investments in demonstrating the safety and efficacy of new technologies before they can be marketed in developing countries. Patent rights provide that security and offer development and marketing leverage for new products.

One option for securing patent rights is the PCT system, but the PCT relies on individual nations having robust domestic IP systems. Though it is not yet a member of the PCT, Bangladesh has been striving to position itself globally as an IP-rights-friendly nation. The recent Bangladesh Patent Act of 2022 is emblematic of these efforts.[99]

The Act is designed to ensure compliance with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and other international standards.[100] For example, the Bangladesh Patent Act extended the patent protection period from 16 years to 20 years, consistent with terms in most nations.[101] It also establishes a concrete judicial system for handling patent cases and a comprehensive list of relief options for patent holders, improving the administrability and efficacy of patent rights.[102]

The average cost to process a patent in Bangladesh, including processing and attorney's fees, sits between $1,000 and $3,000 for most inventions.[103] This is significantly cheaper than costs in the United States and United Kingdom, where filing costs average at $10,000, making Bangladesh an attractive destination for inventors looking for economical patenting solutions.[104]

It is highly likely that by obtaining patent rights Dr. Mitra and his team can continue to innovate, attract more investments, and promote wider dissemination. Dr. Mitra continues to develop the project with the help of Dr. Khan, now of Heriot-Watt University, and the inter-university collaboration will benefit from the support enabled by IP rights. With endless possibilities ahead, the "Multi-Modal Portable Respiratory Rate Monitoring

Device for Childhood Pneumonia Detection" has the potential to be a groundbreaking innovation, revolutionizing healthcare and improving the lives of millions in Bangladesh and beyond.

Intellectual Property at Work: How Serenox Africa is Improving Diagnostic Testing in Sub-Saharan Africa

By Natalie Khoo

Sub-Saharan Africa has long been a recipient of health aid, more so than other developing regions. A call to address the region's pressing healthcare needs and challenges has led to significant investments and developmental aid from donors including international organizations, philanthropists, and multilateral institutions.

While these efforts have played a significant role in improving health outcomes and reducing mortality rates, the focus has predominantly been on treating diseases perceived as threats to global health security. These include zoonotic viruses and multidrug-resistant bacterial strains, with tuberculosis being just one example.[105] As a result, there has been a large emphasis on providing therapeutics such as antivirals, antibiotics, and, in some cases, targeted oncology drugs to curb the spread of such diseases. While treatments have become increasingly available and affordable, they address only part of the problem.

A critical, often overlooked component in addressing such health challenges is accurate and accessible diagnostic testing. Robust diagnostic tools are essential for the accurate identification and management of diseases, enabling timely and appropriate treatments.[106] Yet these essential diagnostic services remain largely inaccessible to roughly 50 percent of the population in sub-Saharan Africa.[107] This is alarming, as the absence of early, precise, and rapid diagnostics can lead to a cascade of negative consequences. As Dr. Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization, stated, "An accurate diagnosis is the first step to getting effective treatment," and "No one should suffer or die because of a lack of diagnostic services, or because the right tests were not available," underscoring the urgent need to bridge the diagnostic gap.[108] Besides hindering timely and appropriate intervention for common and potentially curable diseases, the economic ramifications are also very concerning. Delayed diagnoses often lead to more-severe illnesses, resulting in higher

treatment costs and extended hospital stays. This not only strains the already overburdened healthcare systems in sub-Saharan Africa, but also undermines the overall effectiveness of international aid efforts.

One organization that has risen to the challenge to address the need for accurate and affordable DNA-based diagnostic services in low-and middle-income countries is Serenox UK.[109] A social enterprise spin-out of the University of Oxford, SerenOx UK leverages scientific expertise and intellectual property rights to enable the precise and rapid diagnoses of inherited blood disorders, infectious diseases, and early-stage cancers in sub-Saharan Africa. Through patented bioinformatic analysis of liquid biopsies and licensed machine algorithms, Serenox UK analyzes circulating tumor DNA for multi-cancer early detection, including those caused by infections, transforming the field of diagnostic testing in such regions.[110]

Currently, SerenOx UK holds patents for a noninvasive pre-natal diagnostic test for sickle cell disease in the United States and in Europe (Patent number: US10900081B2, EP2971082A1).[111] These patents in the bioinformatics analysis of liquid biopsies and copyrighted machine-learning algorithms allows SerenOx UK to analyze circulating tumor and viral DNA for multi-cancer early detection, including those caused by infections, by simply drawing blood from the patient.[112] Similarly, by combining affordable rapid-point-of-care carrier lateral flow testing and non-invasive pre-natal diagnosis of haemoglobinopathies from maternal plasma, SerenOx UK created a comprehensive suite of precise diagnostic tests for the most-common monogenic disease worldwide.[113]

Moreover, the DNA sequencing data, produced from its patented technology, is analyzed by Serenox UK and made freely available for research purposes. This not only enhances the value of its patents, but also contributes significantly to research and addresses the dearth of data on the African genome, diversifying the genetic data used in biomedical research. Additionally, this enables partnerships with pharmaceutical companies that require such data to develop new drugs and penetrate new markets.

Serenox UK has already made a significant impact across the region. According to Professor Anna Schuh, the organization has helped around 1,000 children and adults across Uganda and Tanzania, demonstrating the scalability and effectiveness of its diagnostic approach. Its commitment to improving health outcomes is further illustrated by the organization's involvement in clinical research. Serenox UK has funded and supervised clinical trials enrolling 379 children with Burkitt's Lymphoma, a type of cancer that is particularly prevalent in parts of Africa.[114]

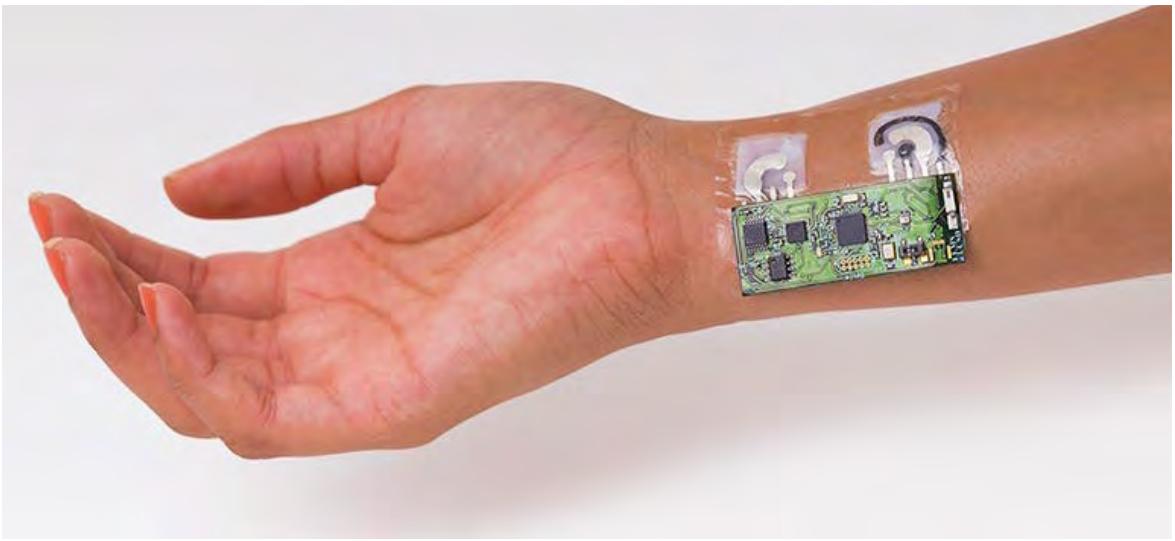
Recognizing the far-reaching effects of Serenox UK's intellectual property and innovative diagnostic technologies, Professor Schuh saw an opportunity to expand the company's services to the rest of Africa. Building on 18 years' experience developing genetic tests for blood diseases and cancer, she founded Serenox UK's sister company, Serenox Africa, the first specialized hematology and hemato-oncology clinic and laboratory in sub-Saharan Africa.[115] Based in Dar-es-Salaam, Tanzania, the team, led by Dr William F. Mawalla, is now offering low-cost, low-maintenance tests for as little as $10.[116] Serenox Africa employs cloud-based data systems that allow remote analysis by experts, eliminating the need to send samples abroad, which can be challenging and costly.[117] This innovative approach ensures timely and accurate diagnoses while leveraging global expertise. Moreover, funding from patients who can afford to pay for services enables Serenox Africa to offer testing more widely to those who are unable to pay, ensuring greater accessibility and equity in healthcare.

In addition to providing cost-effective and accessible diagnostics, a key focus of Serenox Africa is building local capacity and ensuring long-term sustainability. In developing countries like Tanzania, clinicians and scientists often lack sufficient knowledge, exposure, and expertise to produce high-quality laboratory test results, to conduct bioinformatics analyses, and to clinically interpret the results, all of which are crucial for a DNA test's quality and accuracy.[118] Therefore, to address this gap, Serenox UK provides training to ensure the quality of sample processing in the laboratory and to support data interpretation, effectively amplifying the transfer of know-how.

Serenox UK and Serenox Africa's vision to ensure that "patient-near, fast, accurate and affordable testing for key treatable diseases are commonly available to all patients in sub-Saharan Africa" is a testament to the vital role IP rights play in addressing global health challenges.[119] Its success, rooted in Serenox UK's patented technology, has paved the way for ambitious future plans. These include implementing non-invasive prenatal diagnosis for sickle cell disease into routine prenatal work-up, starting with the UK's National Health Service (NHS), running early cancer detection tests in India, and consolidating Serenox Africa's presence in Tanzania.[120]

Dr. Wedyan Babatain Brings Wearable Medical Tech Closer Than Ever

By Douglas Park



Wearable technology, such as smart watches, provides an opportunity to materially increase the ease of use of many medications, improving in turn the efficacy of those treatments.[121] When it's easy to take your pills, you'll take them more regularly and they will work better.

However, many wearable devices are still in their infancy, and it will take some time before they become readily available. The good news is that brilliant scientists like Dr. Wedyan Babatain are making strides in making wearable technology both effective and affordable.[122]

Sometimes medicine is more easily prescribed than taken. Patients in developed nations take their meds properly only about half the time, and roughly one-quarter of all patients in these countries simply forget to take their medications or take them the wrong way.[123]

This lack of adherence causes more than just a waste of good medicine, as well. Failure to take medications exactly as prescribed compromises the efficacy of drugs that require careful maintenance of consistent levels in the patient's body and can double the rates of hospitalization for people suffering diabetes, high cholesterol, high blood pressure, or other heart conditions.[124]

Poor compliance increases resistance to medication as well. A study conducted at the Johns Hopkins Outpatient Center discovered that even a single missed dose materially increased the likelihood of a patient developing a resistance to antiretroviral drugs used to treat HIV.[125] With the global rise in anti-microbial resistance, the possibility of individual patients building additional resistances poses a substantial risk, especially in less-wealthy countries.[126]

Adherence failure even skews the results of research into that medication's effects on a patient demographic, adversely affecting the use of that medication to treat future patients.[127]

The biggest reason for adherence failure is when the treatment is simply too complex for patients.[128] Even taking a single pill once each day can raise difficulties when one considers when in the day that medicine needs to be taken, whether it must be taken with food or on an empty stomach, and whether the medication has dangerous interactions with a patient's other prescriptions.

Many patients with chronic conditions also stop taking their medications when they feel better, not realizing that they feel better only because they are taking their medications.[129] Especially when a medication regimen was a difficult habit in the first place, it may be unduly tempting to give up when a patient feels perfectly healthy.

We can improve medication adherence by clarifying patient-provider communications, of course, but it is also important to make those medication regimens easier on the patient. Wearable devices present a compelling option by automating some of the medication procedures.[130] These devices can provide diagnostic information to both patient and provider in real time and even serve as a drug delivery apparatus itself.[131]

Ease of use can nevertheless pose an obstacle for wearable devices too. Many of these devices are rigid, bulky objects that are not only conspicuously ugly but even uncomfortable to use for extended periods. Dr. Wedyan Babatain therefore focused her doctoral research at the King Abdullah University of Science and Technology (KAUST) into developing wearable medical devices built from flexible graphene that can more easily conform to the dynamic surface of human skin.[132]

Dr. Babatain's device includes a system of sensors, processors, and reservoirs that can automate the detection, diagnosis, and administration of medicines.[133] Though the device has seen only preliminary testing thus far, it presents immense potential for improving ease of use with difficult medications. Even medications such as insulin that are to be administered as needed will benefit from a device that can constantly monitor the user's blood sugar levels and automatically dispense insulin when appropriate.

The device is even manufactured using accessible techniques, including 3D printing and screen printing, making it reproducible by facilities with limited availability to more sophisticated technologies.[134] Dr. Babatain states that this manufacturing process is viable in "low-resource settings and environments," allowing broad use of the technology in areas that are most desperate for medical equipment.[135]

Accessibility as a design theme is consistent even in how Dr. Babatain has documented the development of her device. She has multiple patents associated with her device on file with the World Intellectual Property Organization (WIPO) under the PCT, making the documentation available worldwide.[136]

Patent law includes disclosure and enablement requirements, meaning that any patent issued on an invention involves publication of documents demonstrating how to reproduce that invention.[137] This means that the patent is available to the public even while the invention is still protected by its patent, ensuring that the innovation is shared with the world.

Enablement is an essential piece of how patent law enables innovation. As we have discussed in previous Innovate4Health articles,[138] one of the most common paths for a new invention to reach widespread adoption

is through technology transfer, which relies largely on the enablement elements of patent documentation to facilitate the production of new healthcare innovations like Dr. Babatain's wearable devices.[139]

Through technology transfer, a new invention—mostly commonly created by university researchers—gets a patent that then enables a handoff to parties who can refine the invention into a marketable product. Most university labs are ill-equipped for the kind of iterative testing required to make a product fit for general consumption, much less for mass production, so tech transfer programs connect these researchers with firms that specialize in that kind of refinement and production.

Consider Smartbone, for example, a Colombian startup which created printable jawbone implants.[140] With the help of a patent licensing agreement, Smartbone formed a partnership with distributor Innmetec to make these implants available on a national scale.

Brazil saw a similar benefit from tech transfer in the development of Calixcoca, a vaccine against the effects of cocaine.[141] Researchers at the Federal University of Minas Gerais (UFMG) developed the vaccine and, with the protections of Brazil's analogue to the U.S. Bayh-Dole Act, were able to form a public-private partnership to continue research and development.[142]

Dr. Babatain and KAUST present a similar story. KAUST offers a robust tech transfer program to its researchers, not only to help them protect their work but also to enable them to share that work with the world.[143] The university's mission explicitly includes the "benefit [of] the region" in addition to supporting its innovators.

Enablement and tech transfer are not limited to commercialization, either. Even in cases where an inventor is more concerned about public wellbeing than their own individual profit, patent protections allow a degree of control over the use of the invention that can make sure it is used to improve the lives of others. Inventors can leverage their patent rights to license their invention primarily to non-profit organizations, for example, and then make separate commercial licensing agreements with corporations that can subsidize the more charitable-distribution of the invention.

With the help of KAUST and its technology commercialization office, Dr. Babatain will be able to ensure that her wearable device innovations are made available to the people who most need them. Even if Dr. Babatain is interested only in providing her research to improve upon existing wearable technology, her patent protections and associated enablement will ensure that her brilliant work is responsibly shared with the world.

HydroZitLa Uses Native Flora to Help Fight Kidney Stones

By Douglas Park

Kidney stones have been described as one of the most excruciatingly painful experiences, sometimes considered even worse than childbirth or severe burns.[144] Because the condition is so widespread, treatments are needed all over the world, especially in hot climates like Southeast Asia, where kidney stones are particularly prevalent. Thai university professors have devised a drinkable dietary supplement with both curative and preventive properties to help combat kidney stones.[145]

Kidney stones, also known as renal calculi, result when minerals crystallize in a patient's urinary tract, typically in the kidneys.[146] Once they reach a large-enough size, these lumps can cause blood in the urine, urinary difficulty, and excruciating abdominal pain.[147] Patients are sometimes asymptomatic until their kidney stones cause infections, which can become life-threatening if not quickly treated.

Risk factors for kidney stones vary widely, but the largest factor in their formation is inadequate water intake.[148] Without proper hydration, the urinary tract accumulates minerals more quickly than they can be eliminated via urination. This is especially dangerous in hotter climates, where sweat drains the body's moisture even more quickly.

As a result, southern Asian nations are known as a "stone belt" subject to substantially higher incidence of kidney stones.[149] For example, ultrasound diagnosis identifies the presence of kidney stones (also known as "nephrolithiasis" or "urolithiasis") in 16.9 percent of northeastern Thailand's population at some point in their lives, with preliminary reports indicating an additional 12 percent prevalence of undiagnosed stones in rural areas.[150] By contrast, Germany sees kidney stone prevalence around 4-4.7 percent, while the highest rate is 20 percent in the dry climate of Saudi Arabia.[151]

These rates are also increasing worldwide.[152] Especially in the "stone belt," growing likelihood of kidney stones presents a threat to many populations, and many patients cannot readily afford expensive treatments like extracorporeal shockwave lithotripsy treatment, a noninvasive treatment that effectively vibrates stones apart.[153] Other treatments, such as the urethral insertion of a laser device to break up stones, can be even more expensive, running up to $10,000.[154]

Given that kidney stones can both result from and increase the likelihood of conditions like kidney disease, diabetes, and cardiovascular disease, the dangers of kidney stones are complicated.[155] The issue is further exacerbated by recent research that indicates a correlation between susceptibility to kidney stones and greater oxidative stress.[156]

In essence, oxidative stress refers to the chemical reactions that result from prolonged exposure to oxygen.[157] The process of oxidation has been found to increase the likelihood of cancer, cardiovascular disease, various forms of arthritis, and more. In short, oxidation is a major cause of aging.[158]

All of this brings Dr. Chanchai Boonla and his fellow Chulalongkorn University faculty to their creation of HydroZitLa, a patented liquid dietary supplement that helps prevent buildup of kidney stones.[159] HydroZitLa is a blend of citrates and antioxidants harvested from native Thai flora like the blue pea flower and banana stems. It is dispensed in pouches as a concentrate that can be simply mixed into drinking water and served as a beverage.

In preliminary trials, research has indicated that HydroZitLa materially reduced mineral deposits in the kidneys of rats without imposing any substantial negative side effects. In fact, HydroZitLa appeared to be as effective in breaking down and preventing kidney stones as Uralyt-U, a drug commonly used to treat stones.[160]

HydroZitLa was approved by the Thai Food and Drug Administration in 2019, and the supplement can be purchased from vending machines in various locations around Chulalongkorn University.[161] This availability would not be possible without Dr. Boonla and his colleagues having patent protections on the concoction.[162] Past Innovate4Health articles have described the value of patents in technology transfer programs, and HydroZitLa presents another example of how commercialization and widespread access are made possible by intellectual property.[163]

Even more importantly, the clinical trials needed to determine the efficacy of HydroZitLa are possible only with substantial funding. Even the in vitro and in vivo testing already done cost money, and human trials are even more expensive.[164] Investment in those trials comes only with the security provided by patent law.

Clinical trials are not merely a procedural hurdle, either, but a necessary step in refining the safety and efficacy of medicine. Another previous Innovate4Health article has examined the value of traditional medicine in modern healthcare, and HydroZitLa represents a similar opportunity.[165] Blue pea flower and banana stem have been used in Thai traditional medicine for some time but combining them with citrate has proven to be an invaluable blend of traditional and modern medicine in the treatment of kidney stones.

While traditional medicine itself is not patentable, the improvements made to it through modern science are exactly the innovations that intellectual property seeks to promote. With the proper protections and collaboration between public and private entities made possible by tech transfer and patent rights, kidney stones can be treated as easily as drinking a tasty beverage.

Chapter 4: Challenge: Increasing Efficacy and Removing the Detrimental Side Effects of Existing Therapies

Bio is Tech: Re-Imagine Disease Detection Through Koniku's Innovative Odor Surveillance System

By Natalie Khoo

Advancements in silicon and computer technology over the past decade have been nothing short of astounding. From shrinking the computer chip, developing semiconductors, to producing everyday consumer goods, these innovations have driven tremendous progress in various fields including life sciences and medicine. Yet at the heart of humanity's greatest scientific feats lies a more powerful, advanced system that can easily outclass and outmatch any super processor—the neuron.

With over 86 billion of these microscopic units interconnected in every human brain, we witness a biological computer with an unparalleled ability to process information.[166] Where silicon computers divide tasks among various interacting units—logic, arithmetic, and memory—each neuron integrates these functions seamlessly.[167]

The natural efficiency and compactness of the neuron inspired Oshiorenoya Agabi, a Nigerian neuroscientist, to think beyond traditional silicon-based chips. He envisioned creating a new kind of chip that integrated live neurons themselves, harnessing the inherent capabilities of actual neurons rather than merely emulating them.

Together with a team of scientists that includes bioengineers and molecular biologists, Agabi established Koniku, a synthetic biotechnology company.[168] Koniku's flagship product, the Koniku Kore, is the world's first neurotechnology device.[169] It is a wetware chip that fuses live neurons from mice stem cells with silicon, creating a smell cyborg capable of tasks beyond the reach of conventional technology.[170] This smell cyborg, which is

smaller than an iPhone and weighs less than 600 grams, consists of a neuron-silicon processing core, sensors that recognize smells, and an electrode that reads and writes information inside the neurons.[171] Specifically, the core houses 128 active neurons, more than 50,000 hidden neurons, and 640 electrodes.[172]

Similarly, this innovative device has the potential to transform how we approach disease detection and health monitoring. By combining live neurons with silicon into a chip, the Koniku Kore can autonomously and intelligently read the air and detect various volatile organic compounds, mimicking the function of a dog's nose.[173] This is achieved by engineering proteins in biological neurons to create precise protein particle interactions that can function as sensors, amplifiers, and biological signal processors for various health conditions and environmental hazards, including the detection of cancer and drugs like amphetamines and fentanyl.[174]

Additionally, the smell cyborg is equipped with a comprehensive data processing and analysis system. The biological-silicon hybrid sensors collect real-time data on airborne compounds and transmit it to cloud services via IoT capabilities.[175] This continuous stream of information then feeds into Koniku's growing database, which forms the foundation of its machine learning backend. As the system processes and analyzes the data, it becomes increasingly adept at classifying and extracting valuable insights from the vast array of odors that impact human life. As a result, this end-to-end approach enables Koniku to offer a wide range of services, from generating detailed reports to supporting advanced analytics, potentially revolutionizing fields such as early disease detection, environmental monitoring, and personalized health management.[176]

Koniku's innovative neuron-based chip has not gone unnoticed. The company has garnered significant interest from major corporations like AstraZeneca, Boeing, and Cisco, securing substantial investment and partnerships. Since its launch, Agabi and his team have raised $1 million in funding from investors such as Presight Capital, IDO Investments, SoftBank, and HealthCap Africa, to name a few.[177] According to Agabi, Koniku has generated $10 million in profits through deals with the aviation and pharmaceutical sectors. It is projected that the market for Koniku Kore could reach up to $145 billion in the upcoming years.

Moreover, the success of Koniku goes beyond its financial achievements and market impact. The company has positioned itself as a leader in the neurotechnology field. Building on its success with the proprietary wetware technology stack, the team created the Koniku Technology Integrator System, a community platform designed to facilitate the development and deployment of solutions for businesses ranging from startups to Fortune 500 companies. Koniku has partnered with Airbus to develop solutions for aircraft and airport security, leveraging Koniku Kore's ability to detect specific chemicals associated with security threats and Airbus's engineering capabilities across the United States. This collaboration marks a pivotal milestone in Koniku's joint go-to-market strategy.

Koniku has demonstrated its commitment to innovation through an extensive portfolio of patent filings. Currently, the company holds a patent to protect an electrode that provides superior signal-to-noise ratio recordings from neurons (Patent number: JP6858769) thereby enhancing the quality and accuracy of the recordings compared to traditional two-dimensional or planar electrodes. In addition to this key patent, Koniku has filed numerous other patents covering different aspects of its technology, including the integration of live neurons with silicon, methods for engineering proteins in biological neurons, and advanced data processing

techniques (Patent numbers: WO2024026229A1, WO2022250988A1, US20220263510A1).[178] By securing strong intellectual property protection, Koniku ensures that it can continue to innovate and commercialize its technology while protecting itself from imitation by competitors.

As we enter a new age of biotechnological innovation, Koniku leads the charge in redefining what is possible. The company's journey illustrates that the most profound advancements often come from looking inward, to the very building blocks of life itself. Their maxim, "Bio is Tech," embodies their belief that any sufficiently advanced technology is indistinguishable from nature.

Calixcoca: A Shot at Sobriety
Brazil's Innovative Vaccine Aims to Revolutionize Addiction Medicine

By Tatyana Norman-Webler

Cocaine use disorder (CUD) is a significant public health problem with limited treatment options. While studies are underway, there is no FDA-approved pharmacologic therapy.[179] The primary treatment is behavioral therapy.[180]

But what if people battling CUD didn't experience cravings at all? What if we could vaccinate against cocaine addiction, or any addiction, the way we vaccinate against measles or the flu?

With the visionary leadership of Frederico Garcia, a team of researchers at the Federal University of Minas Gerais in Brazil have created a novel anti-cocaine vaccine called *Calixcoca*.[181]

After completing his doctoral studies in France in 2011, Dr. Frederico Garcia returned to his hometown of Belo Horizonte, Brazil, and witnessed firsthand the devastation of the crack cocaine epidemic.[182] As a professor of psychiatry at the Federal University of Minas Gerais (UFMG), Garcia witnessed the devastating consequences of addiction in his community as local prosecutors penalized mothers suffering from cocaine use disorder by taking their babies at birth. Garcia explained that this is not the time to separate a mother from her newborn baby because this moment is pivotal in the child's development and often in the mother's sobriety.

While Brazil does not produce cocaine, the country acts as a bridge for cocaine to travel from Peru, Colombia, and Bolivia to the United States and Europe.[183] Brazil is one of the world's largest consumers of cocaine, second only to the United States.[184] Cocaine trafficking and addiction are so challenging and common that a district in Sao Paulo has been dubbed "Cracolândia" or "Crackland."[185]

The large number of Americans who also have substance abuse issues further illustrates the global seriousness of the problem. A 2022 survey found that 48.7 million Americans battled substance use disorder (SUD), and of those, 27.2 million battled drug use disorder (DUD).[186] 5.3 million people reported using cocaine in 2022, with the highest use among "young adults aged 18 to 25."[187] A Kaiser Family Foundation poll found that two-thirds of Americans have been impacted by addiction, with 27 percent reporting that a family member had struggled with addiction to an illegal drug.[188]

While the obvious solution is abstinence, people battling cocaine use disorder are at a high risk of relapse due to the drug's powerful effects on the brain and cravings that are exceptionally difficult to fight.[189]

The goal of research into *Calixcoca* is to stimulate the production of antibodies that latch onto cocaine molecules and prevent them from crossing the blood-brain barrier, making them unable to reach the dopamine receptors that cause a feeling of euphoria. Basically, users would no longer get "high" from cocaine.[190]

The tricky part is that cocaine by itself is not immunogenic—the molecules are too small for the immune system to recognize. Most vaccines would address this by attaching the cocaine molecules to larger proteins that the immune system can process, but that requires a prohibitively complex process of sterilization and refrigeration.[191]

Instead, the Calixcoca team used large carrier molecules called calixarenes.[192] They attached molecules that imitate the structure of cocaine molecules to these calixarene carriers to train the immune system to combat anything that looks like cocaine.

A 2021 study in mice demonstrated immunological potential and the ability of both calixarene carriers to bind to cocaine-like molecules to prevent them from reaching the brain.[193] They have since successfully demonstrated the safety and effectiveness of the final product, UFMG-VAC-V4N2, i.e., *Calixcoca*, in monkeys.[194] With $10 million in government funding, the team hopes to begin human trials later this year.

The team plans to start with a group of 30 individuals in Phase I clinical trials and progress to 300 individuals in Phase II clinical trials. UFMG partnered with hospitals and clinics to recruit patients with CUD who have abstained from cocaine use because of their admission. Clinical trial participants would receive a total of three intramuscular doses of *Calixcoca*.

Clinical trials will monitor abstinence not only through regular urine screens, but also by sociological and psychological metrics. How soon were participants able to obtain a job? Have they reconnected with family?

Garcia hopes that anti-cocaine vaccines will not only treat individuals battling CUD but also serve as a preventative treatment for fertile women who battle CUD. He explained that only one-quarter of pregnant women with CUD manage to stop using while pregnant.

Intellectual property has been integral to *Calixcoca's* development. With the help of UFMG's technology transfer office, Garcia's team secured a patent to protect their novel anti-cocaine molecules from the Brazilian Patent Office in 2017 (BR 10 2017 015955 8), and their patent was granted in the United States.[195] Garcia hopes that patent protection and successful Phase I trials will help raise more funding from private firms. *Calixcoca* recently won the Euro Health Innovation Award in October 2023, securing the top prize of 500,000 euros.[196]

The Brazilian government sees the potential in this research. Garcia shared that the government recently invested $1 billion in building a state-of-the-art biopharmaceutical research center. In 2004, Brazil enacted the Innovation Law (Law No. 10973/04), modeled after the U.S. Bayh-Dole Act, which incentivizes innovation and public-private collaboration by affording patent protection to publicly funded research at universities.[197]

The law was last amended in 2018 to create mechanisms that bring "more legal security to the parties around the technologies that are jointly developed."[198] Sao Paulo is already known as the "largest innovation ecosystem in Latin America," and with the help of federal investment, robust patent protections, and UFMG's technology transfer program, Garcia hopes that Brazil will become the world's leading biopharmaceutical pipeline.[199]

Garcia noted that the drug that revolutionized cardiovascular treatment—Captopril and the derivative family of ACE-Inhibitors that followed—was invented in Brazil using venom from a poisonous Brazilian viper.[200] Now, Frederico Garcia and the *Calixcoca* research team hope to transform millions of lives by revolutionizing addiction medicine and transforming Belo Horizonte into a biopharmaceutical innovation hub.

Innovative Cure For All: How CurASeal's Plant-Based Technology Advances Bleeding Control and Wound Healing

By Natalie Khoo

Wound care and hemorrhage management are essential aspects of medical treatment, particularly in surgical procedures. Traditionally, these practices have relied on a combination of dressings, antibacterial agents, and antiseptics to prevent infection, promote healing, and control bleeding.[201] However, the growing prevalence of antibiotic-resistant bacterial strains and the potential for antiseptics to damage healthy tissue have increasingly called the effectiveness of these conventional methods into question. As a result, there has been a growing shift toward more advanced antimicrobial wound care solutions which are often enhanced with bioactive compounds.

The demand for such advanced solutions has become even more apparent in recent years due to disruptions in global supply chains, particularly during the COVID-19 pandemic. Countries in the Middle East and North Africa (MENA) region such as Egypt and Saudi Arabia, which have long depended on imported medical supplies, encountered significant challenges in obtaining these life-saving products. With approximately 90 percent of medical supplies coming from outside the region, namely the United States and Germany, the MENA medical device import market was valued at over $13.1 billion in 2022.[202] These challenging times have underscored the critical need for local production of medical devices, which is essential not only for ensuring supply chain resilience but also for reducing costs and increasing accessibility to essential healthcare products.[203]

Rooted in the principles of "innovating medical devices for today, tomorrow and what's needed next," InCurA, an Egypt and Saudi-based IP deep-tech company, is setting out to democratize access to high-quality medical devices in the MENA region.[204] Founded by Mousa Salem and Wesam Sarhan, InCurA focuses on developing a pipeline of cost-effective hemostatic products that not only meet but exceed global standards.[205] Leveraging its unique know-how and cutting-edge technologies, InCurA utilizes the latest advancements in machine learning to develop a novel line of AI-optimized devices which have now been licensed for production in Saudi Arabia with major industry players such as ROYAH Pharmaceuticals and Cighala Healthcare.[206]

Among InCurA's groundbreaking products is CurASeal, a 100 percent plant-based starch hemostatic powder designed to control bleeding effectively and rapidly.[207] Unlike conventional hemostatic agents, CurASeal employs a patent application Nano-in-Microsphere technology, complemented by perforated microparticles that enable rapid blood clotting in seconds.[208] This innovative structure ensures complete absorption by the body within 48 hours. Similarly, the starch-porous microparticles feature a unique concave, red-blood-cell-like structure and nanopores on the surface, allowing for instant and complete blood penetration, setting it apart

from existing products like Arista (BD's hemostatic powder) and SURGICEL Powder (J&J). which only offer partial or no penetration.

Besides, CurASeal's versatility makes it suitable for a wide range of surgical applications, including vascular, urology, cardiothoracic, orthopedic, general, and plastic surgeries. Available in 1gm and 3gm sizes, CurASeal is engineered to perform optimally in narrow and hard-to-reach surgical sites, providing the quickest blood clotting activity.[209] This is achieved through three synergistic mechanisms: concentrating cellular and protein components for clot formation, amplifying thrombin formation to accelerate the coagulation cascade, and exhibiting antifibrinolytic activity to maintain a stable clot.[210]

InCurA's success can be attributed to its robust IP portfolio, which covers various facets of its composition and manufacturing process. For instance, the product's starch microparticles are specifically designed for enhanced blood penetration and adhesion, which significantly improves its efficacy compared to other products on the market. Additionally, by eliminating enzymes from the formulation, InCurA has managed to reduce production costs, allowing CurASeal to be competitively priced and accessible to markets with critical needs, such as those in Africa. This strategic intellectual property management has not only safeguarded the company's innovations but also ensured its ability to meet urgent healthcare needs efficiently.

This success is further bolstered by the company's strategic initiatives and recognition in the industry, which have garnered significant recognition and investment. InCurA has secured funding from prominent investors, including Kaust Innovation Ventures, to support its mission of democratizing access to high-quality healthcare solutions and expanding its operations.[211] Furthermore, the company's achievements have also been acknowledged through prestigious awards, including the ID&E Disruptors Award for co-founder Wesam Sarhan, and a spot on *Forbes* 30 Under 30 Middle East for co-founder Mousa Salem.[212] These honors highlight InCurA's transformative role in advancing medical technology within the MENA region.

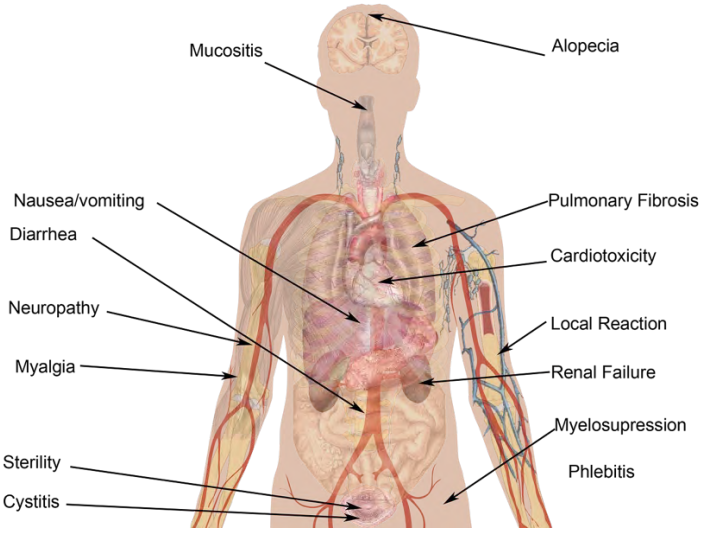
By addressing the "Valley of Death"—the challenging gap where biomedical research often fails to reach commercialization—InCurA has established a comprehensive business model that connects market needs with innovative laboratory research. This synergy facilitates efficient manufacturing and distribution throughout the MENA region.[213]

Through strategic partnerships and a dedication to locally produced, high-performance medical devices, InCurA is not only tackling present challenges but also setting new benchmarks for the future of medical care. As the company broadens its product repertoire and augments its manufacturing prowess, it stands ready to play a pivotal role in ensuring essential healthcare solutions are within reach for all, especially in regions where they're most desperately needed.

Andes Biotechnologies Makes Sense of Cancer Treatments with Antisense Technology

By Douglas Park

Cancer is such a pervasive threat that it has become a common metaphor for anything loathsome, yet the treatments are often nearly as bad as the disease. Both chemotherapy and radiotherapy harm healthy parts of the body while also attacking cancer.[214]



By contrast, many new cancer treatments take a more targeted approach. Andes Biotechnology, a Chilean drug development startup, is currently engaged in clinical trials for a new drug that combats unchecked cell growth using novel "antisense" technology.[215] This drug would target cancerous cells without directly affecting normal cells and may even prove effective against all forms of cancer.[216]

Cancer is currently one of the three most common causes of death in 177 of 183 countries worldwide.[217] Nearly one-sixth of all deaths are the result of cancer, and that rate jumps to one-in-four among non-communicable diseases.[218] Globally, over 20 million new cases of cancer developed in 2022, and roughly 9.7 million deaths resulted from cancer.[219]

Those deaths are becoming more common, too. The percentage of the population who succumb to cancer each year rose by 21 percent from 1990 to 2019.[220] This increase is primarily due to the average human lifespan increasing, in that more people survive long enough to develop cancer.

Because the disease results from flaws in our normal cellular growth, the chances of those processes going awry only increase with time.[221] While there is no evidence to suggest that younger populations are any more susceptible to cancer-related deaths now than in the past, it does seem likely that cancer will be the next major obstacle to improving the human lifespan.

However, available treatments for cancer still leave much to be desired. Chemotherapy involves regular doses of toxic agents that inhibit cellular growth in both cancerous and healthy cells.[222] As with any drug treatment, there is a material risk that cancerous cells will develop resistance to chemotherapy drugs.[223]

Side effects of chemotherapy may include toxicity buildup in kidney or liver as the organs try and fail to filter out the drugs, possibly resulting in organ failure.[224] Because the medicine targets cells that multiply quickly, it also has adverse effects on a patient's hair follicles, gastrointestinal tract, and bone marrow production.

Radiotherapy involves breaking down the DNA in cancerous cells with the targeted application of intense radiation and has its own limitations.[225] Subjecting the body to radiation damages healthy tissues and can result in symptoms that resemble radiation sickness.[226] Some of these risks can be mitigated with specialized technology that precisely focuses the radiation exposure on cancerous tissues, but these machines can cost hundreds of millions of dollars and are in high demand with rising global cancer rates.[227]

Chemotherapy and radiotherapy are generally combined to optimize efficacy, but even then success is measured by how long patients survive after initial diagnosis.[228] In the United States, 31 percent of patients succumb within five years of diagnosis, 53 percent within ten years, and 82 percent within twenty years, making cancer the second most common cause of death in the United States.[229]

In 2018, Chile saw over 50,000 cancer diagnoses and nearly 30,000 deaths from cancer.[230] Chilean patients also face a higher rate of both diagnosis and mortality than other Latin American nations.[231] The risk of developing cancer before the age of 75 is 19.1 percent in Chile but 18.9 percent in Latin America, and the risk of dying of cancer before 75 is 9.3 percent in Chile but only 8.9 percent in Latin America overall.

However, Andes Biotechnologies stands at the frontier of cancer treatment. The Chilean startup is currently in the first phase of clinical trials for its new Andes-1537 drug.[232] The invention uses a novel "antisense" technology that targets cancerous cells based on identification of precise RNA strands.[233]

Unlike how chemotherapy poisons cancerous cells only marginally more than healthy cells, Andes-1537 identifies cancerous cells by their unique genetic sequences and leaves healthy cells largely unaffected. Even better, preclinical studies indicate that Andes-1537 demonstrates enough versatility that it might be able to treat any kind of cancer.[234]

Andes Biotechnologies could not have made it this far without patent protections, though. The startup was able to commence clinical trials only after receiving $10 million from investors, a sum that would have been impossible for the startup to supply on its own.[235]

Investors like Austral Capital have not only praised Andes' brilliant innovation but also the startup's commitment to intellectual property rights. Andes Biotechnology has patents for Andes-1537 filed through the Patent Cooperation Treaty, providing it patent rights in at least 16 patent systems worldwide.[236] Because of these protections, Austral Capital fund manager Felipe Camposano expressed excitement on behalf of the company, noting that Andes Biotechnologies "has the scientific and management expertise to translate the company's vision into reality."[237]

Because of this enthusiastic support from investors, Andes Biotechnologies now has an Investigational New Drug (IND) Application active and approved by the U.S. Food and Drug Administration (FDA), allowing them to proceed with clinical trials.[238] The best part is that Andes' IND approval came in 2015 and it announced transition into the second half of phase 1 clinical trials in 2019, so Andes-1537 is already well on its way to improving the lives of cancer patients around the world.

Clinical trials are a difficult filter, however. Only 25 to 50 percent of all new cancer drugs that reach randomized clinical trials produce successful treatments, and every one of those drugs requires millions of dollars in funding to even enter trials.[239] While cancer drugs consistently receive some funding from the National Institutes of

Health (NIH) through its "cooperative clinical trial infrastructure," it is the only disease that receives this funding.[240]

Instead, the vast majority of drugs require substantial private support from investors to make it through clinical trials, and without patent rights those firms would not provide that support. Fortunately for cancer patients around the world, the PCT and its member nations offer robust patent protections, enabling companies like Andes Biotechnologies to push their new drugs through clinical trials and onto the market. With these partnerships built on patents, investors can use their wealth for the benefit of humanity, innovators can afford to research healthcare innovations, and, most importantly, people around the world can get the latest in cancer treatments.

Pioneering Cell Banking with Paper-Based Cryopreservation—A New Era in Life Sciences

By Natalie Khoo

In the life-sciences sector, intellectual property serves as a vital intangible asset for innovation. It not only offers legal protection that fosters the development of groundbreaking technologies but also often acts as a primary driver of a company's market valuation. This is particularly crucial in the fight against complex diseases like cancer, which remains a leading cause of death worldwide. With one in six deaths globally attributed to cancer, the role of intellectual property in incentivizing and protecting life-saving innovations becomes even more significant.[241]

Besides, developing new drugs and medicines, especially for cancer, is an extremely costly and time-consuming endeavor. On average, bringing a single drug from discovery to market takes over a decade and costs between $2.6 billion and $3.2 billion. The drug discovery process involves several critical stages: discovery and development, preclinical testing, and clinical trials.

Initially, in the discovery phase, researchers test their hypotheses by identifying potential therapeutic targets and screening thousands of compounds. This is followed by preclinical testing, where promising compounds are evaluated in the lab using cell cultures and in animals to assess their safety and effectiveness. If these tests are successful, the drug candidate progresses to clinical trials, where it undergoes rigorous testing in humans to determine its safety, effectiveness, and optimal dosing.

However, traditional preclinical testing methods face significant limitations, particularly in cancer research. Two-dimensional cell cultures, typically grown in petri dishes, fail to accurately replicate the three-dimensional

structure of human tumors, leading to unreliable results and delays in development.[242] To address these shortcomings, researchers often turn to animal models. While these may offer more insights into key biological responses, they present their own set of challenges. Animal testing is ethically contentious, expensive, and time-consuming. Similarly, animal models often display poor translational results as they cannot fully mimic human tumor biology due to the profound differences in anatomy and physiology between animals and humans.[243]

Prompted by these challenges, Ayoub Glia, who hails from Morocco, had a goal to reduce reliance on animal testing and redefine preclinical testing by providing robust testing models.[244] Together with a group of researchers from New York University Abu Dhabi, Glia created high-throughput arrays of cell aggregates (i.e., bringing cells in close proximity to facilitate communication through direct cell–cell contact), or three-dimensional tumor models, on a single paper platform for cryopreservation and drug screening applications.[245] This patented technology allows for the long-term storage of three-dimensional tumor arrays, which can be subsequently thawed for drug testing (Patent numbers: WO2018231993, US20210169070).[246] Moreover, this method not only addresses the ethical and accuracy concerns associated with traditional cell and animal testing but also offers a cost-effective, space-saving, and simple approach to cell preservation.

Additionally, this innovation utilizes inexpensive, bench-top three dimensional printing technology to create masks with small holes. These masks are used to selectively treat special paper (silanized paper) with a simple chemical process that changes specific areas of the paper, thereby creating tiny, highly localized spots called "virtual microwells" that attract water. Cells naturally gather and form clusters within these microwells, hereafter referred to as microspots, and are surrounded by water-repellent areas called "virtual barriers" that prevent the cells from mixing between different spots. This approach ensures that the paper-based three-dimensional tumor arrays can be successfully cryopreserved and thawed for on-demand use. Furthermore, the potential applications of this technology are vast, including its use as off-the-shelf components that can be stacked together to build advanced and sophisticated tumor models.

In relation to generating these tumor models, the developed paper platform offers several major advantages. First, the patterning procedure on paper is simple and scalable, taking no longer than 20 minutes.[247] The printed mask is reusable at least 15 times for patterning, and the generated arrays of the three-dimensional tumor models cost less than $5 per paper chip, making it a highly cost-effective solution.[248] Another significant advantage is its ability to efficiently cryopreserve cell aggregates for extended periods, potentially up to several months, with minimal impact on cell viability, morphology, and metabolic activity. This feature not only saves substantial preparation time and effort but also reduces overall costs.

From a commercial perspective, this opens up possibilities for supplying cryopreserved three-dimensional tumor models to research laboratories worldwide, similar to the distribution methods used by cell biobanks. This method could also potentially be applied to cancer cells derived directly from patient biopsies, facilitating streamlined drug screening studies applicable to precision medicine.

Moving forward, by providing a more accurate representation of human tumor biology, Glia's innovation addresses the limitations of traditional preclinical testing and offers a promising solution for more reliable and ethical drug development processes. This breakthrough underscores the critical role of intellectual property in nurturing and protecting life-saving innovations, ultimately paving the way for faster and more effective cancer treatments.

Chapter 5: Challenge: Making Personalized Medicine Accessible to More Patients

Colombian SmartBone Provides Accessible Custom Craniofacial Implants #Innovate4Health

By Douglas Park

Head injuries can have devastating, lasting effects, from persistent pain to social discomfort, self-esteem issues, and even risk of death.[249] Implants can repair skull structure, but their cost and availability can be a major obstacle, especially in less wealthy nations.[250] Colombian companies Smartbone and its partner Innmetec are using patented technology to change that, developing customizable and cost-effective prosthetic implants to meet demand in South America.[251]

Craniofacial injuries from accidents or congenital defects such as cleft palate are global problems. Traumatic injuries to the head and face from car and work accidents are distressingly common worldwide, especially in Latin America, where intracranial injury occurs at a rate 1.5 times higher than the global average.[252] Similarly, congenital defects causing craniofacial anomalies (CFAs) afflict millions. For example, roughly 1 in 600 newborn infants worldwide are born with cleft lip and cleft palate.[253] These injuries burden individuals with disabilities and social challenges while imposing significant costs on society.

Often, the only effective solution for these injuries is the use of craniofacial implants to replace the damaged or missing parts of the skull. However, implant materials must meet strict standards—they need to minimize rejection risk, resist corrosion, provide sufficient strength, avoid imaging interference, and allow normal bone regrowth.[254] Titanium is the only broadly available material that meets all requirements, but medical grade titanium is an expensive import for most countries.[255]

Smartbone, a university spinoff led by engineer Catalina Isaza, has developed an innovative and patented compound of ceramic and polymer that provides an accessible alternative to titanium.[256] The material combines the polymer polyetheretercentone with a ceramic made from hydroxyapatite. The resulting implant resembles human bone, fuses well with naturally grown bone, and promotes bone growth. This material can even be used in children, reducing the need for replacement as they age. It also avoids issues with metal implants like discomfort from thermal conductivity. Crucially, the compound can be easily shaped for customized patient implants.

Director Isaza, who wanted to be a doctor as a child, saw this unmet medical need in her country and dedicated her engineering expertise to solving it. Smartbone offers customized implant designs that restore both function and aesthetics, while reducing wait times, risks, and costs by one-third compared to imported options.[257] By the end of 2020, Smartbone devices had already treated 267 patients, and that total only continues to grow.[258]

Smartbone was spun out of a collaboration between EAFIT University, Colombia's school of administration, finance, and technology, and CES University, who are both members of the Bioengineering Research Group (GIB).[259] GIB was founded in 1997 as an initiative to promote scientific advancement and design in medical and dental technologies. The initiative has 44 research groups, including the one that resulted in Smartbone.

This collaboration among universities in GIB also created an entity for technology transfer. Technology transfer moves promising discoveries made in research labs into the private sector for translation into applied medical technologies that benefit patients.[260] As university technology transfer offices do in the U.S., Europe, and other countries, GIB manages its researchers' IP as well as regulatory certifications and compliance. GIB has a portfolio of 52 patents for all its research groups.

IP rights are essential to technology transfer success stories such as Smartbone. Research labs typically do not develop applied technology—it's a long, risky, and expensive process, often requiring skills and procedures incompatible with researcher's interests and experience. Fortunately, spinoffs, startups, and established companies are willing to make the necessary investments needed to develop technology fully, but they need a prospect for return on their investment. IP rights provide the necessary security for such investments, providing an opportunity to benefit if development is successful.

The results can be seen in the work of Smartbone. The company has procured two patents through the Colombian Superintendence of Industry and Commerce. The 12088195 patent, granted in 2014, covers a technique for the embossing of metal sheets into appropriate shapes for prostheses.[261] The NC2016/0000434 patent, granted in 2019, covers an articulated design for a temporomandibular (jawbone) implant that allows a natural range of motion.[262] These patents were the foundation for Smartbone's investment in the development of its customizable implants.

The Smartbone patents have also enabled further business collaboration to bring the implants to more patients. In 2021, Innmetec entered a license deal to distribute Smartbone implants, which included a license to the patents. Although the implants had already been used in patients, Jose Rodrigo Isaza, general director of Innmetec, observed that the deal has enabled their national distribution.[263]

IP rights enable such important partnerships to the benefit of both businesses and patients. Adriana García, director of Innovation EAFIT, said that Innmetec was a key strategic ally for broadening the reach of Smartbone implants because of its market share and expertise.[264] IP rights allow such win-win collaboration to happen. Innmetec received access to cutting-edge technology, Smartbone was able to reach a larger market, and IP rights provided a basis of trust between partners and security against potential copiers.

Chosen as one of *MIT Technology Review's* Innovators Under 35 Latin America in 2023, Catalina Isaza now plans to take Innmetec to other Latin American countries.[265] Her story demonstrates how intellectual property rights can promote and propagate homegrown, accessible medical device innovation, even in resource-limited environments. With IP protection helping to secure investment and collaboration, Innmetec and Smartbone are bringing customized, life-changing implant solutions to hundreds of patients in Colombia and beyond.

Tinnitus Perú Offers Individualized Treatment for Tinnitus Deliverable Remotely

By Sophia Sterling

Tinnitus, a debilitating hearing problem, afflicts roughly 740 million people globally.[266] Tinnitus is an intolerable sound perceived by the sufferer without any external auditory source. Although not painful, tinnitus can severely degrade people's quality of life by making it impossible to listen, concentrate, or even fall asleep.[267]

To address this epidemic, Giannina Ofelia Honorio founded Tinnitus Perú, a company that specializes in the diagnosis and treatment of tinnitus.[268] One of Tinnitus Perú's revolutionary innovations is technology that provides customized rehabilitation therapy to drastically reduce the perception of or even eliminate tinnitus altogether.

Tinnitus is especially prevalent in South America, where 21.9 percent of the population suffers from ringing in their ears.[269] A wide range of common issues lead to tinnitus, including noise exposure, hearing loss, medications, ear wax, or head and neck injuries. Between 10 and 25 percent of adults worldwide suffer from tinnitus. This rate increases with age, with more than one-third of adults over the age of 65 suffering from the condition.[270] People with tinnitus also are more prone to depression and anxiety.[271]

Currently, there is no cure for tinnitus, just treatments that mitigate the effects.[272] Hearing aids have been used to make external sounds easier to hear over the ringing, and wearable sound generators can help override the ringing. Medication also can help with sleep issues. None of these remedies reduce the ringing itself, however.

Exacerbating the problem for many tinnitus sufferers is lack of access to ear, nose, and throat specialists. Ear, nose, and throat (ENT) specialists, also known as otolaryngologists, are in short supply globally, with only 2.19 clinicians available per 100,000 people.[273] This scarcity is particularly acute in LMICs, where the density of ENT specialists is significantly lower compared to high-income countries. Despite housing 85 percent of the global population affected by ENT conditions like head and neck cancer and hearing loss, LMICs have only 0.09 to 2.85 ENT clinicians per 100,000 people, while high-income countries have 5.13 specialists per 100,000 residents, highlighting the urgent need for both capacity building and novel solutions to increase accessibility of treatments.

Honorio, the founder and CEO of Tinnitus Perú, identified the need for more accessible treatments for tinnitus through her experience as a volunteer firefighter.[274] Honorio, an industrial engineer and university lecturer with a master's degree in neuroscience, saw how prevalent tinnitus was among her fellow firefighters. She founded Tinnitus Perú, a 30-person startup with a multi-disciplinary team of doctors, engineers, technologists, and clinicians, to address the challenge.[275]

Tinnitus Perú has developed a cutting-edge biomedical electronic system that creates personalized rehabilitation plans for individuals suffering from tinnitus.[276] The treatment process begins with an initial hearing examination to diagnose the patient's specific hearing problem. Once a tinnitus diagnosis is confirmed, Tinnitus Perú's proprietary hardware and software are used to test the patient and develop a model of the sounds they perceive. This innovative electronic system employs various frequencies of sound signaling to pinpoint the exact type of persistent noises the patient is experiencing.

Honorio highlights the importance of this technology in helping patients communicate their experiences: "One of the biggest problems is that tinnitus patients don't know how to explain what sounds they hear and no one believes them. With this electronic system they can identify it, and now they can communicate it to their relatives."[277] By demonstrating the sounds patients perceive and providing them with the tools to describe these sounds, Tinnitus Perú's system offers a positive effect even before further treatment begins.

Following the initial screening, the electronic system uses the information gathered to create a personalized treatment plan for each patient.[278] This plan consists of a specific sequence of sounds designed to help reduce the ringing sensation. Patients typically undergo 8 to 14 sessions, which can significantly reduce and even eliminate the tinnitus. To track the effectiveness of the treatment, the patient's progress is measured every three sessions. Most patients experience at least an 80 percent reduction in their tinnitus symptoms, with the perception of ringing being significantly reduced or even completely eliminated after several months of treatment.[279]

In addition to the sound therapy, Tinnitus Perú's treatment program includes psychological support to help patients cope with the emotional and mental aspects of tinnitus. "With this technology we are able to improve people's quality of life. It's nice to see people change so much . . . as stress is strong due to tinnitus," Honorio said. This holistic approach ensures that patients receive comprehensive care tailored to their individual needs. To make the treatment more accessible, Tinnitus Perú offers telemedicine services through its app, allowing patients to receive their personalized treatment plans and support remotely, from the comfort of their own homes.

Today, Tinnitus Perú treats over 400 patients every month, and this number continues to grow. The company hopes to help the million or more patients suffering from tinnitus in Latin America by expanding its reach into Chile and Bolivia.[20] Ultimately, the company sees its therapy as having a global reach.[280]

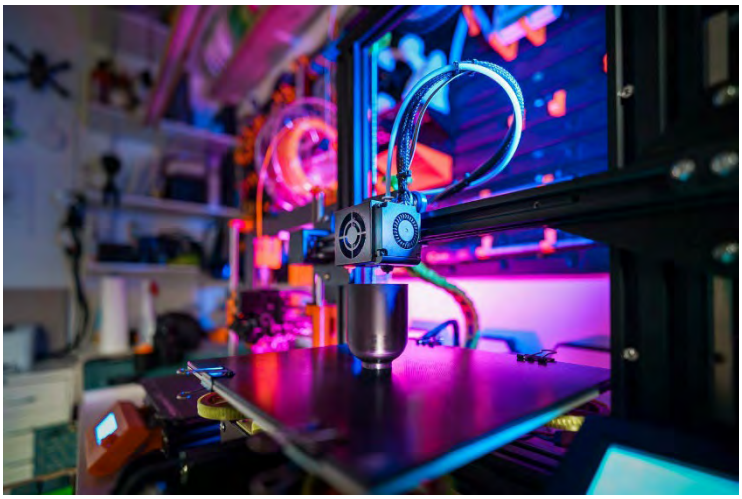
The company has received several awards and accolades for its innovative technology. *MIT Technology Review* recognized Honorio as one of its "Innovators Under 35 Latin America 2023."[281] Tinnitus Perú reached the finals of the Start Jerusalem contest, organized by the Peruvian Government and the Embassy of Israel in Peru, and took second place in Brain Chile's international competition for innovative startups.[282] Thanks to the latter competition, Brain Chile, a tech incubator, became Tinnitus Perú's first investor.[283]

Tinnitus Perú recognizes that secure intellectual property rights are crucial to its ability to expand its operations and secure further investment. Tinnitus Perú has obtained both patent and trademark protection in Perú.[284] It recognizes that in order to fulfill its ambitions to expand internationally, it will need to secure IP rights in other countries. A more expansive patent portfolio with an international reach increases the likelihood of investment, as it will secure a broader potential market for Tinnitus Perú's innovations.[285]

Tinnitus Perú's groundbreaking technology offers hope to the millions of people worldwide who suffer from the debilitating effects of tinnitus. By developing a personalized, accessible, and effective treatment that directly addresses the root cause of the condition, Giannina Honorio and her team have demonstrated the power of innovation to tackle global health challenges. The company's commitment to securing intellectual property rights, both in Perú and internationally, underscores the crucial role that patents and trademarks play in fostering innovation and attracting the investment needed to bring life-changing technologies to market. As Tinnitus Perú continues to expand its reach and refine its technology, it serves as an example of how innovative solutions, backed by strong IP protections, can improve the lives of people around the world.

Pill.AR: Printing Personalized Medicine with MESO-PP

By Douglas Park



Medication typically follows a "one-size-fits-all" paradigm which does not always meet patients' unique needs. Aside from dosage and frequency, every patient receives the same drugs for the same conditions even though no two patients are identical. Despite its efficiency, the "one-size-fits-all" paradigm poorly suits many patients.

This paradigm for medication makes less sense when one considers that other treatments are more individualized. No surgery is exactly like another, and prosthetics must be highly personalized to avoid orthopedic distress. Similarly, differences among patients—e.g., genetics, other medications, personal circumstances—make standardized pills and other dosage forms less than optimal.

Innovators are now rising to the challenge of personalizing medication, and Argentinian startup Pill.AR has developed a promising solution. Personalized medications are custom-tailored to meet the specialized needs of individual patients.[286] One innovation to advance the personalization of medication entails using three-dimensional (3D) printing to produce small-batch, customized medications.[287] Pill.AR has developed a particularly promising method for 3D printing medications, the Melting Solidification Printing Process (MESO-PP), a novel way to produce small-batches of medications.[288]

More customized medication offers many benefits that would improve treatment for patients globally. For example, some people have adverse reactions to the form of or inactive ingredients in topical medications for skin conditions such as skin atrophy and hormonal imbalances.[289] Personalized medication can avoid such problems by customizing doses based on an individual patient's present condition, other medications, and genetic profile. Customization has many benefits including greater safety, efficacy, cost-effectiveness, and better rates of patient compliance.[290]

Because conventional pharmaceutical manufacturing is geared toward large batches and is therefore not well suited to personalized medicine, 3D printing is a popular choice for producing small-batch medicines.[291]

However, 3D printing has its limitations, too. Many printing materials have not yet been approved for human use, and most printing methods require solvents or high temperatures that risk damaging the medicinal content. Many of these methods also require specialized operation such as loading plastic filament, formulating gels, controlling the flow of powder, or drying forms.

To address these issues, Pill.AR designed its MESO-PP technique for printing medications. MESO-PP uses a pre-mixed solid material as a substrate that can be stored for later use as necessary. The substrate is then heated

to a temperature no greater than 60 degrees Celsius, where it liquefies and the medication is added. The mixture can then be extruded into the desired shape and size as appropriate for the personalized medication plan.

Pill.AR describes numerous advantages to its MESO-PP process. The technique does not use any solvents that could destabilize the drug or impose additional costs for drying, and it avoids the use of potentially hazardous resins. It uses a relatively low temperature that allows production of increasingly commonplace thermosensitive drugs.[292] Most import to the accessibility of personalized medicine, MESO-PP does not require specialized processes and uses cheap and portable printers that are relatively simple to operate.

Pill.AR describes opportunities to improve patient compliance as the main advantages of MESO-PP. Medication can be printed with pleasant flavors, bright colors, or novel shapes to make them more palatable to children. The printed forms can contain personalized combinations of drugs, vitamins, and nutraceuticals, substantially simplifying a patient's daily medication regimen. The pills can even be printed around diagnostic devices to facilitate patient monitoring, and the printing process can be automated to improve efficiency and minimize upkeep costs.

The company hopes to address a local concern with their invention. According to Pill.AR, less than 10 percent of Argentina's pharmacies produce individualized medicine forms, in large part due to legislative restrictions on the preparation and storage of medications. MESO-PP will enable community pharmacies to produce personalized medicines for their patients without expensive equipment or extensive training, making effective medication accessible for lower-income communities. Pill.AR also believes that the production process will remove a substantial amount of packaging involved with the blister packs normally used for medication, thus limiting the generation of waste.

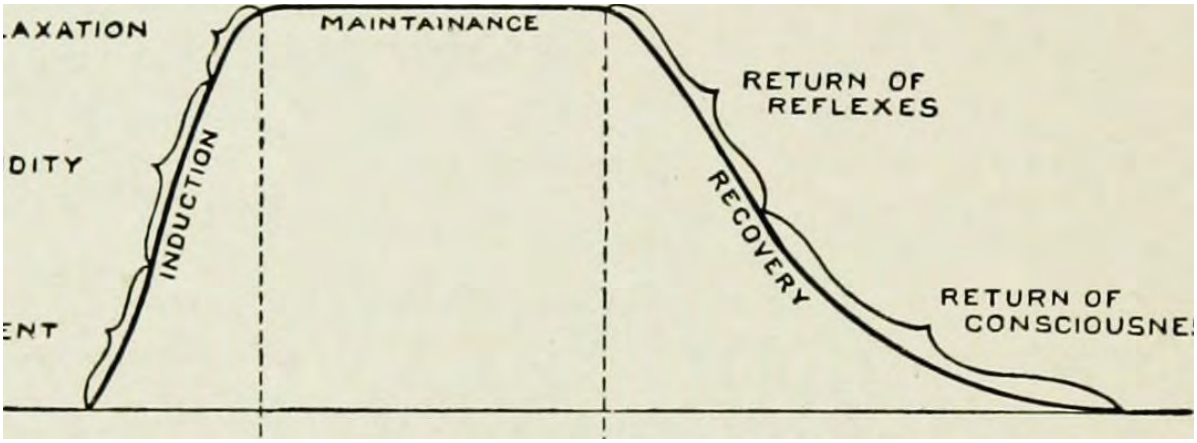
Intellectual property protections were a key enabler of Pill.AR's efforts. Pill.AR describes the company as "born from" its patent on MESO-PP, secured through the Argentinian IP system.[293]

Patent rights are essential to protect investments in innovative manufacturing processes such as this. A great virtue of MESO-PP is that it is an accessible and affordable solution using standard equipment, but that virtue makes it all too easy to duplicate. Innovators such as Pill.AR's founders could not justify investing the time and money of themselves and their investors without the security of IP rights.

Fortunately, IP rights have provided the foundation Pill.AR needed to proceed from the idea of accessible printed medicine to the practical reality of MESO-PP. The innovation promises to help many patients in Argentina and around the world.

Colombian Knockout Monitor Prevents Anesthesia From Wearing Off During Surgery

By Douglas Park



Waking up in the middle of surgery is usually the stuff of horror stories, but it does occasionally happen in real life. Awareness during anesthesia, known as "intraoperative awareness," happens to roughly 1 or 2 out of every 1,000 patients.[294] Fortunately, researchers at Universidad de La Sabana have developed Knockout Monitor, an AI-assisted monitoring system that makes general anesthesia a more consistent and reliable process.[295]

Intraoperative awareness is a worldwide public health problem. The effects of intraoperative awareness can be devastating, even beyond the pain experienced during surgery. Immediate psychological effects may include anxiety and feelings of helplessness, paralysis, and impending death.[296] Patients may also develop persistent symptoms such as nightmares, anxiety, depression, and post-traumatic stress disorder (PTSD).[297] Avoidance of medical care is another common side effect, exacerbating any future conditions a patient may suffer.[298]

Ensuring that a patient remains properly anesthetized for the duration of surgery is a complex task. Anesthesiologists manage both the proper dosage of sedatives, often applied repeatedly throughout surgery, and continuously monitor the patient's vitals.[299] These specialists are highly trained and competent professionals, but each patient has unique needs to prevent intraoperative awareness.

Each case requires "a careful preoperative evaluation" of factors including age, sex, American Society of Anesthesiologists (ASA) Physical Status Classification, and drug tolerance.[300] The ASA Practice Advisory Task Force also recommends reviewing the patient's medical records, conducting a careful physical examination, and even patient or family interviews to help identify patients who may be susceptible to intraoperative awareness.[301] Despite all these efforts, diagnostic tools are imperfect and too many patients still awake on the operating table.

Dr. Daniel Botero Rosas decided to reduce the odds of patients awakening from anesthesia by developing a better diagnostic tool. He had observed that doctors must all too often diagnose anesthetic depth entirely "according to knowledge and experience," so he set out to develop a better tool .[302] Dr. Botera works in the Universidad de La Sabana's department of morphophysiology, and he teamed up with his university colleague

Oscar Leonardo Mosquera, engineer and doctor of biosciences.[303] Together, they developed the Knockout Monitor system.

Botero and Mosquera's system combines innovative digital signal processing techniques and a custom-built AI platform to classify a patient's anesthesiologic depth in real time. The invention permits doctors to maintain sedation levels safely and reliably.[304] Knockout Monitor merges several steps of diagnosis into a single process, including gathering biological signals, monitoring neurological activity, processing and measuring those signals, and finally collating all of that data into usable diagnoses.[305]

Universidad de La Sabana lauds the Knockout Monitor system for making patient monitoring more efficient by limiting the necessary amount of human interaction to ensure patient safety.[306] As opposed to the conventional practice of constantly monitoring muscle movement, ocular reflexes, respiratory and perspiratory patterns, ECG, blood pressure, heart rate, and more, the Knockout Monitor system processes all diagnostic data simultaneously and more quickly than a human can, allowing anesthesiologists to manage patient sedation more efficiently and effectively.[307]

Mosquera says that this project "aims to strengthen the knowledge-based economy," a sector where Colombia shows promise.[308] As in countries throughout the world, Colombia has skilled and knowledgeable researchers such as Botero and Mosquera working in universities and other research institutions. Transforming their ideas into applications that can help patients requires technology transfer, the process through which research labs move their innovations into the private sector where they can be further developed. The development of Knockout Monitor is a prime example of the benefits of technology transfer.[309]

Intellectual property rights are crucial to ensure the success of tech innovations such as Knockout Monitor. Researchers such as Dr. Botero and Mosquera usually do not have the resources to turn their innovations into applied technology. The development process for life-sciences technology is a long, expensive gamble that often requires skills and knowledge regarding regulatory compliance and testing outside the experience of research labs.

Fortunately, startups, spinoffs, and established companies have the resources and know-how to turn an idea into reality, given assurances that their investment can produce returns. With IP protections afforded by patent law, these inventors have the security necessary to form partnerships with investors, providing an opportunity to benefit from successful development to inventors, investors, and patients alike.

The Knockout Monitor system is moving into the clinical trials and testing stage through the work of Unisabana Hub, the university's dedicated knowledge transfer unit.[310] Unisabana Hub has taken advantage of the Patent Cooperation Treaty to secure patents in several countries, including both the United States and Colombia.[311]

With those patent protections, Knockout Monitor is substantially more likely to secure the funding necessary to conduct clinical trials with Clinica Universidad de La Sabana and Hospital Universitario de La Samaritana.[312] Once the system has passed clinical trials, Dr. Botero and Mosquera can spin off a business firm from the university to handle marketing and distribution, in keeping with the transfer strategy prescribed by the university's Office of Transfer of Research Results (OTRI).[313]

The two innovators plan to share their invention outside of Colombia with other nations, including the United States and Brazil.[314] With the benefits of the PCT international patent system and the collaborative processes of tech transfer, Knockout Monitor may soon enter the international market and bring both peace of mind and less traumatic medical procedures to patients around the world.

Chapter 6: Challenge: Reducing the Global Burden of Non-Communicable Diseases as Life Expectancy Increases

Trailblazing Colombian Startup Is Changing the Lives of Children Living With Cerebral Palsy

By Natalie Khoo

Laura was a five-year-old girl who lived in Maya, Cundinamarca, a rural town in Colombia. Unlike other children, Laura faced a unique set of challenges, for she was 1 out of 300,000 children in Colombia born with cerebral palsy.[315] Cerebral palsy is an umbrella term used for a group of neurological disorders that appear in infancy or early childhood that permanently affect an individual's ability to control body movement and muscle coordination.[316] It is caused by abnormal brain development or damage to the developing brain that occurs before, during, or shortly after birth. As a result, it disrupts the brain's ability to control motor functions such as maintaining balance and posture, thereby making it the most common cause for childhood motor disability.

For Laura and the 18 million people affected by cerebral palsy across the world, the reduction in motor repertoire, coupled with the loss in the quality of movement can result in devasting consequences such as paralysis, especially if there is inadequate rehabilitation performed.[317] Unfortunately, accessing appropriate rehabilitation services can often be a challenge for many families and children like Laura. In Colombia, approximately 70 percent of children with cerebral palsy live in remote areas where resources are scarce and access to specialized healthcare services including physical therapy and rehabilitation are largely unavailable.[318] But one company - KitSmile, a Colombian health startup - has tackled this challenge by democratizing access to rehabilitation treatments for children living with cerebral palsy.[319]

Inspired by Laura's story, Leidy Cuestas and Lina María Camargo, the founders of KitSmile, created GymSmile - an 8-in-1 at-home rehabilitation kit for children between the ages of 2 and 12 living with cerebral palsy.[320] Unlike current rehabilitation devices, GymSmile has a multifunctional and interactive design that goes beyond

improving posture, enhancing motor skills, and promoting balance. It has the ability to address a wide range of different therapy and everyday needs such as stretching, eating, and resting.[321] Specifically, it draws upon the Bobath concept, a neurodevelopment treatment approach that leverages sensory and motor pathways in the brain to facilitate normal movement and regain motor control.[322]

With its comprehensive design, GymSmile has revolutionized the field of rehabilitative care by offering families a cost-effective and portable alternative for ongoing physical therapy and support.[323] As physical therapy is a first-line treatment for children with cerebral palsy, GymSmile ensures consistent access to daily therapy by integrating the rehabilitation journey into the comfort of their own homes, without the financial burden of frequent clinical visits or specialized equipment. Besides being cost-effective, a key aspect that the team at KitSmile considered while designing this innovative intervention was the durability and long-term impact this device could provide for patients. Hence, each rehabilitation kit is built to last for 10 years. By creating adjustable modules that range from 50 to 170cm, it enables caregivers to easily adjust the device to accommodate to the height and size of children as they grow, ensuring extended use and value. Long-term durability is also highlighted by the fabric on the medical solution, which is engineered to withstand high temperatures and liquids, while facilitating air circulation to prevent discomfort and eliminate bedsores.

Currently, KitSmile's medical innovation has positively impacted over 205 children and their families, demonstrating the team's commitment to improving the quality of life of low-income children with disabilities.[324] By redefining accessible, effective, and innovative rehabilitation solutions, KitSmile, under the leadership of Leidy and Lina, has received 21 awards, including ITIF's Call for LATAM Health Champions and The Bizz Awards, to name a few. Nevertheless, none of this would have been possible without the protection and support provided by intellectual property rights.

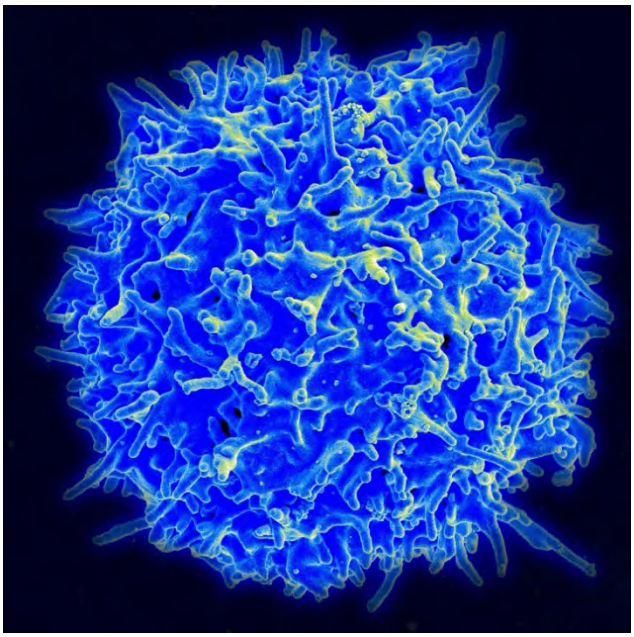
From the outset, Leidy recognized the importance of safeguarding KitSmile's innovative solutions from competitors through patents and trademarks. However, like many innovators in developing countries, she faced initial challenges in applying for a patent. Determined to overcome them, she sought support from legal experts at Lloreda Camacho, a law firm in Bogota, Colombia, which helped her navigate the complex Colombian patent system. As a result, KitSmile was granted a patent and two trademarks for the therapeutic device, making Leidy Cuestas the youngest woman in Colombia to obtain a patent for a health invention.

The startup has also received significant financial backing—the company raised a total of $8 million from Colombian investors such as Vaki Capital and BBVA Momentum.[325] In turn, KitSmile expanded its operations, reaching more children in need across Colombia. KitSmile's innovative business model, which uses a buy-one-give-one approach, has not only made its product accessible to low-income families, but has also garnered attention and support from stakeholders such as Tania Zapata and Alexander Torrenegra, who donated 50 million pesos to support the cause.[326] Furthermore, through partnerships with hospitals, government entities, and other organizations, KitSmile has been able to scale its impact, providing essential rehabilitation support to children and families who would otherwise lack access to such services.

In essence, KitSmile's success story highlights the critical role of intellectual property rights in protecting and enabling innovation, especially in developing countries. By safeguarding their inventions, Leidy and Lina have not only secured their place in the market but have also paved the way for more accessible and effective rehabilitation solutions for children with disabilities. Through their innovative approach, KitSmile continues to make a meaningful difference in the lives of countless families.

NexCAR19: The Future of Lymphoma Treatment in India, and IP's Essential Role

By Brian Thomson



Existing treatments for leukemia and lymphoma are not always effective. Even when treatment succeeds, it may be too expensive or simply inaccessible, especially in less-wealthy countries such as India. Fortunately, Indian companies like ImmunoACT are actively developing novel treatments like the recently approved NexCAR19 T-cell therapy.[327]

According to the National Cancer Institute (NCI), in 2020 over 570,000 people worldwide lost their lives to blood cancers, including leukemia and lymphoma, and estimates suggest that 70,000 of those deaths happen in India.[328] India's Shalby Hospitals network states that India sees one new case of blood cancer every five minutes.[329]

Many patients in India are unable to treat their cancers because of inadequate accessibility or financial hardships. While these treatments are cheaper in India than in other nations, the average out-of-pocket cost still exceeds $4000 per patient per year, if treatment is available at all.[330]

However, recent progress in the development of new treatments presents an opportunity to improve both the availability and affordability of cancer treatments in India and other less-wealthy nations. One major impetus to this forward progress is the domestic development and production of innovative drugs and therapies in India.

One of these innovations is ImmunoACT's NexCAR19 therapy, developed in partnership with the Indian Institute of Technology Bombay (IIT).[331] This new drug allows a patient's immune system to more fully combat leukemias and B-cell lymphoma, and ImmunoACT hopes that NexCAR19 will provide relief where other treatments and therapies have failed.[332]

This new therapy is also noteworthy for being one of the first cancer therapies developed and created entirely within India.[333] NexCAR19 was recently approved by India's Central Drugs Standard Control Organization (CDSCO), paving the way for its implementation as the first of its kind in the Indian market.[334]

ImmunoACT's website describes in detail how NexCAR19 is administered.[335] First, white blood cells are extracted from the patient at the hospital and placed in a special containment vessel called a "Leukopak," then shipped to an ImmunoACT facility under refrigeration.

At the ImmunoACT facility, scientists modify these white blood cells to target the patient's cancerous cells.[336] The scientists develop a culture of the same white blood cells to build up multiple doses' worth, which are then cryopreserved and extensively tested to ensure identity, purity, safety, and potency. The doses of modified white blood cells are then shipped back to the hospital, where the patient receives special chemotherapy to condition their body for the intravenous infusion of the modified white blood cells.

ImmunoACT and IIT began development of NexCAR19 in 2015 and spent eight years developing and testing it.[337] The patients who participated in these trials suffered from either leukemia or lymphoma and had already attempted more conventional therapies with little or no success.[338] During testing, 58 percent of patients experienced a complete remission of their symptoms, and another 12 percent experienced partial remission.[339] Based on these numbers, NexCAR19 could save hundreds of thousands of lives every year if made available worldwide.

The biggest hurdle to broad availability is the cost to develop, produce, and distribute cancer therapies. The cost of research alone for a given cancer drug/therapy can exceed $1 billion, and only about one in a dozen treatments studied in early-stage clinical trials make it to the market.[340] Even when those new treatments fail to reach the market, pharmaceutical companies still need to recoup those costs to afford new clinical trials, without which new drugs will never become available at all.

One way to recoup these research costs is through the sale of successful new drugs. However, if competitors can copy a drug without taking on any R&D costs themselves, then they can sell it for less than the original drug developers could. To prevent this freeriding, the original developers need to obtain patents on their innovation.

Patents grant developers a temporary right to exclude others from freeriding on the developers' investments in their inventions.[341] This allows the pharmaceutical companies to attempt to earn a return on their investments and incentivizes investment from third parties. Without these returns, pharmaceutical companies would be unable to continue funding the development of additional drugs and therapies, and no new treatments would become available to patients.

Prior to the 1990s, obtaining pharmaceutical patents in India was next to impossible because the Patents Act of 1970 made methods of treatment and mere mixtures of known substances unpatentable.[342] This stifled pharmaceutical innovation for decades, crippling India's ability to compete in the global innovation economy.

Fortunately, the Patents Act of 1970 was amended and made more permissive after India became a member of the World Trade Organization. An amendment to India's Patent Act in 2005 allowed pharmaceutical patents on new chemical entities or improved efficacy with known entities.[343]

While still more restrictive than patent systems in most other nations, these amendments have enabled more inventors to obtain patent protections in India. Because of these changes, healthcare innovations have started to take off in India in recent decades.

For example, IIT has filed for patent protections on NexCAR19 through the Patent Cooperation Treaty has sought patents in India and the United States.[344] The PCT allows IIT to more easily pursue concurrent protections in up to 155 countries.[345] These patent rights have enabled ImmunoACT and IIT to attempt to recoup the resources they have invested in developing NexCAR19.

Moreover, with a patent, ImmunoACT was able to secure the funds necessary to develop NexCAR19 and have the financial backing to consider development of future cancer treatments. Innovators like ImmunoACT and

IIT themselves rarely have the funds necessary for the long and incredibly expensive development and testing for new pharmaceutical therapies like NexCAR19. It is therefore essential that they work with outside investors to fund this stage of NexCAR19's development. Patent protections are essential for attracting such outside funding, as patents protect the investors' contributions as well.

The development of cancer treatments like NexCAR19 has helped to put India on the map when it comes to healthcare research and development. India has the potential to become a pharmaceutical powerhouse with its wealth of brilliant scientists and abundance of resources, and the recent changes in India's IP laws empower companies and research institutions like ImmunoACT and IIT to invest time and resources into developing drugs like NexCAR19. Having stronger IP protections will unleash this pharmaceutical potential, allowing Indian companies and scientific institutions to preserve and prolong the lives of patients across India and around the world.

Caring Cross and Brazil's Fundação Oswaldo Cruz Collaboration Increases Access to Life-Saving CAR-T Cell Therapy in Brazil

By Natalie Khoo

The quest to find effective treatments for life-threatening oncological, infectious, and genetic diseases has been a relentless pursuit in the health and life science field, driving researchers to explore new frontiers of innovation and discovery. In recent years, one of the most promising and innovative solutions that has emerged is the chimeric antigen receptor (CAR)-T cell therapy, a form of immunotherapy, which enlists and strengthens the power of a patient's immune system to attack tumors.[346] CAR-T cell therapy has shown remarkable success in treating blood cancers, particularly lymphomas, some forms of leukemia, and most recently, multiple myeloma.

CAR-T cell therapy represents a revolutionary breakthrough in cancer treatment, harnessing the potential of the body's own immune system to combat cancer cells. By ingeniously engineering a patient's T-cells (a type of immune cell), it can express chimeric antigen receptors (CARs) on their surface.[347] These engineered CAR-T cells can precisely recognize and bind to specific proteins expressed in cancer cells, enabling them to seek out and destroy malignant cells. Similarly, where traditional treatments have led to failure or relapse, this innovation offers the potential for long-lasting remissions and, in some cases, even cures for these diseases.[348]

Despite the excitement surrounding the transformative potential of these advanced therapies, the prohibitively high costs of CAR-T cell therapy, exceeding $350,000 per dose, have created a significant barrier to access, particularly for patients in developing countries, including Brazil.[349] However, recent collaborations between Brazil's Fundação Oswaldo Cruz (Fiocruz), a foundation from the Brazilian government's Ministry of Health, and Caring Cross, an American non-profit dedicated to accelerating the development and access to advanced

therapies for patients around the world, has demonstrated a pioneering approach to overcoming this challenge.[350]

Through this partnership, Caring Cross will transfer its proprietary technology, expertise and training to Fiocruz's Bio-Manguinhos Institute, Brazil's leading vaccine and biologics manufacturer.[351] The collaboration, funded by Brazil's Ministry of Health, aims to develop, manufacture, and commercialize CAR-T cell therapies for the Brazilian population and ultimately all of Latin America.[352] Subsequently, the technology transfer from Caring Cross to Fiocruz will enable Bio-Manguinhos to locally produce innovative CAR-T cell therapies and lentiviral vectors for leukemia and lymphoma as well as create a platform to expand a pipeline of advanced therapies for the treatment of other diseases in the future.

By leveraging Fiocruz's manufacturing capabilities and Caring Cross's innovative processes, the partnership aims to provide CAR-T cell therapies at a significantly reduced cost, making them more accessible to Brazilian and Latin American patients. By enabling local and cost-efficient production, this collaboration will not only provide affordable access to CAR-T cell therapies for the Brazilian public health system, but it will allow access to critical materials and training needed to manufacture CAR-T cells for other organizations in LATAM.[353] Moreover, treatment will be available free of charge to the population, and the cost to the Brazilian public health system would be reduced to 10 percent of the amount currently charged in Europe and the United States, dropping to $35,000 per dose.

It is imperative to recognize the critical role of intellectual property in facilitating this technology transfer. Caring Cross has developed proprietary manufacturing processes and distribution models that significantly reduce the cost burden associated with CAR-T cell therapies. As CEO Boro Dropulić highlighted, "The high cost for CAR-T cell therapies provides an opportunity for innovators like Caring Cross to change the way these medicines are developed and how they are provided to the patients that need them."[354] Robust intellectual property protection has enabled Caring Cross to transfer its decentralized manufacturing model, which allows the final cell product to be produced at a reduced cost at the hospital or point-of-care rather than sent to a centralized manufacturing hub.

Brazil is well-positioned to become a regional leader in the development and dissemination of affordable CAR-T cell therapies and has other ongoing partnerships. These include a collaboration between the Cell Therapy Center of Fundação Hemocentro de Ribeirão Preto, the Federal University of São Paulo, and the Butantan Institute, which are currently conducting ongoing clinical trials with CAR-T cell therapies, with so far promising results.[355] To date, 14 patients have been treated with CAR-T cell therapy through these trials, experiencing 60 percent tumor remission.[356] Additionally, the Brazilian Patent and Trademark Office database currently has over 30 patent applications related to CAR-T cell technology, with most filings from 2019 onwards, indicating growing domestic investment and commercial interest in this field.[357]

Moving forward, the future of CAR-T cell therapy in Brazil looks promising. The collaborative efforts between research institutions, pharmaceutical companies, and government entities have demonstrated a pioneering approach to overcoming the significant barriers to accessing these advanced therapies in developing countries. By addressing challenges to access and fostering an environment of technology transfer, we can enable life-saving treatments to reach underserved populations worldwide. Ultimately, this partnership between Caring

Cross and Fiocruz exemplifies the power of innovation, intellectual property protection, and global cooperation in advancing healthcare and improving the quality of life for countless individuals battling life-threatening diseases all around the world.

Itolizumab Provides Relief from Psoriasis, Covid-19, and More

By Joshua Villers

Every day people live with an unrelenting distress etched into their skin by severe plaque psoriasis, a chronic autoimmune condition characterized by red, raised, scaly patches on the skin, often accompanied by intense itching and pain. For some, however, this condition transcends mere inconvenience and becomes a relentless force that dictates daily life and affects self-esteem, social interactions, and more.

Fortunately, India has produced numerous therapeutic breakthroughs in the treatment of chronic plaque psoriasis. One drug in particular, itolizumab, has shown promise in providing relief to patients affected with not only psoriasis but asthma, COVID-19, and more.[358]

Psoriasis reduces the quality of life and inflicts many psychosocial problems on the affected individual. In addition to persistent itchiness, discomfort, and pain, psoriasis can also cause social friction and even discrimination based on the patient's visible disfigurations. In fact, one study discovered that psoriasis leads to a decrease in quality of life comparable to the experiences of people suffering from cancer, depression, diabetes, and other such major conditions.[359]

A study from 2019 indicates that over 4.6 million people suffer from psoriasis worldwide, and plaque psoriasis accounts for roughly 90 percent of all cases.[360] Approximately 20 percent of patients suffer from psoriasis so severe that they need whole-body treatment, and the chronic inflammatory nature of psoriasis means that patients suffer cycles of relapse and remission that require "on-and-off" treatment schedules.[361]

Individuals with severe plaque psoriasis often must navigate a minefield of treatment options, from topical creams to systemic medications, each with its own set of limitations and potential side effects. Despite the array of therapies available, many patients still struggle to find relief, caught in a constant battle against their own skin.

To combat plaque psoriasis, Indian biopharmaceutical company Biocon launched itolizumab under the brand name ALZUMAb as an innovative biologic treatment for acute psoriasis. The drug combats psoriasis by inhibiting the improper immune response that causes psoriatic blemishes.[362] According to Biocon, itolizumab also offers a gentler treatment process with relaxed dosing schedules and longer breaks between treatments.[363]

Biocon's innovation—and, just as importantly, its patents on that innovation—has attracted foreign investment in research not only the use of itolizumab for psoriasis but also for other conditions and diseases. In 2022, U.S. biotechnology firm Equillium licensed rights from Biocon. With partners like Equillium, Biocon has been able to conduct research into secondary indications for itolizumab. Though the drug was originally tested in India for efficacy against plaque psoriasis as early as 2013, the continued research and development—possible only with the protections that patents provide for such extensive investments—created a family of patent applications, pending in the United States, Australia, Canada, and New Zealand, covering methods of using itolizumab to treat severe asthma.[364]

Biocon and Equillium's investments in itolizumab also proved valuable during the COVID-19 pandemic, as itolizumab shows promise in treating COVID-19. Cuba first tested this possibility in July 2020 and later that same month granted the drug limited approval for use to treat COVID-related acute respiratory distress syndrome.[365] Building on Cuba's research, an Indian study showed that itolizumab significantly reduced mortality in patients hospitalized with similar COVID-related conditions.[366]

With patent protections, Biocon has established a solid foundation for domestic manufacture to provide itolizumab as an affordable alternative for COVID treatment in India. The drug averages just over $106 per vial, making the full course of four vials cost around $425, making itolizumab substantially more affordable than comparable treatments with tocilizumab at up to $670 per vial.[367]

These medical advancements do not come without substantial investment, however. Biocon holds 299 patents for small molecules, 982 patents for biologics, and an exclusive licensing deal with Equillium for methods of use of itolizumab.[368] Because of its robust patent portfolio, Biocon has been able to secure the funding necessary to conduct R&D on itolizumab resulting in treatments for psoriasis, asthma, and COVID-19.

Investors are crucial to the development of new drugs, but they are even more important to research into additional uses for drugs. Safe and effective drugs are impossible without extensive research and clinical trials, which themselves are incredibly expensive. Though sources of funding vary for different stages of drug development, the crucial final stages receive funding primarily from venture capitalists and pharmaceutical firms themselves.[369]

It suffices to say that investors favor opportunities with high chances of return, and the market exclusivities that come from patents are the most secure way to ensure that drug development provides a return. This is especially true for development of drugs that have been on the market for some time, as expiration of exclusivity or the availability of generic alternatives means that further research into additional uses for the original drug is unlikely to be profitable.

This poses a problem for research into drugs that might be useful to treat other diseases, because these secondary indications rarely arise except from regular, widespread use. As a result, strong patent protections are even more important to drug development for secondary indications than for initial research and development.

Intellectual property has therefore been instrumental in Biocon's ability to safeguard its pioneering drug, itolizumab, enabling the company to expand into international markets. Furthermore, it has facilitated a positive feedback loop of innovation, allowing Biocon to channel profits from one generation of drugs back into research and development, thus propelling the creation of subsequent generations of therapies.

Alzheimer's Disease Next Game Changer: TauRx Pharmaceutical's Novel Tau Aggregation Inhibitor

By Natalie Khoo

The advancements in medicine, public health and living standards in recent decades have significantly increased the global life expectancy by more than six years—from 66.8 years in 2000 to 73.1 years in 2019.[370] In tandem, the rise in life expectancy has also led to the growing prevalence of age-related diseases particularly Alzheimer's disease and related dementias (ADRDs), which typically result from a variety of diseases and injuries that affect the brain.[371]

Currently, ADRDs affect 55 million people worldwide, with Alzheimer's disease accounting for 50 to 70 percent of all cases.[372] This is concerning as ADRDs are known to have a severely debilitating effect on quality of life due to the gradual decline in cognitive functions, including memory, reasoning, and verbal capacity.[373] In the same year, ADRDs are responsible for 33.1 million disability-adjusted life years (DALYs) lost, making it the seventh leading cause of mortality and morbidity among older adults globally.[374]

Furthermore, the implications of ADRDs are profound and far-reaching, impacting societies and economies worldwide. In 2019, the global cost of dementia care was estimated to exceed $1.3 trillion, a figure that is forecasted to rise to $2.8 trillion by 2030.[375] Notably, approximately 50 percent of these costs are attributed to care provided by informal caregivers, such as family members and close friends, with women accounting for 70 percent of this caregiving.[376] These caregivers often bear a significant burden, providing an average of five hours of care and supervision per day—a commitment that brings emotional, physical, and financial challenges.

One of the hallmark pathological features of ADRDs is the accumulation of abnormal tau proteins in the brain.[377] Normally, tau proteins help stabilize microtubules, which are essential for maintaining the structure and function of neurons. However, in ADRDs, abnormal chemical changes cause these tau proteins to detach from the microtubules and aggregate to other tau molecules, resulting into tangles (neurofibrillary tangles) inside neurons.[378] These tau tangles disrupt the normal synaptic communication between neurons, leading to significant cell death and the subsequent cognitive decline observed in patients.

Given the central role of tau in the progression of ADRDs, emerging evidence suggests that targeting tau pathology has become a promising approach in the quest for new and effective treatments. TauRx Pharmaceuticals, a leader in Alzheimer's disease research, has focused on this approach.[379] The company's innovative drug, hydromethylthionine mesylate (HMTM), is a novel tau aggregation inhibitor (TAIs) designed to be an affordable, accessible, oral therapy that targets the formation of tau tangles in the brain.[380] The 4mg oral tablet works by promoting the dissolution of existing tau tangles and prevent further aggregation of tau proteins, thereby preserving neuronal function and slowing cognitive decline.[381]

Founded in Singapore in 2002, TauRx Pharmaceuticals has dedicated itself to developing treatments for neurodegenerative diseases, particularly those involving tau pathology. The company's commitment to addressing the unmet needs of Alzheimer's patients is underscored by its extensive patent portfolio. TauRx holds "composition of matter" patents and "use" patents that cover the application of its TAIs for the treatment and prevention of Alzheimer's disease and frontotemporal dementia (FTD).[382] With 836 granted patents and 120 pending, TauRx has established a strong intellectual property position that not only protects its innovative therapies but also positions the company as a leader in the field.[383]

Moreover, TauRx's lead compound, HMTM is the only drug targeting tau for Mild Cognitive Impairment.[384] It has shown promise in clinical trials, with the Phase 3 LUCIDITY trial demonstrating its potential to slow cognitive decline in patients with mild cognitive impairment and mild to moderate Alzheimer's disease. Additionally, the UK's Medicines and Healthcare products Regulatory Agency has accepted the company's Marketing Authorization Application for HMTM, and they are working closely to accelerate the availability of this medicine in the UK.[385]

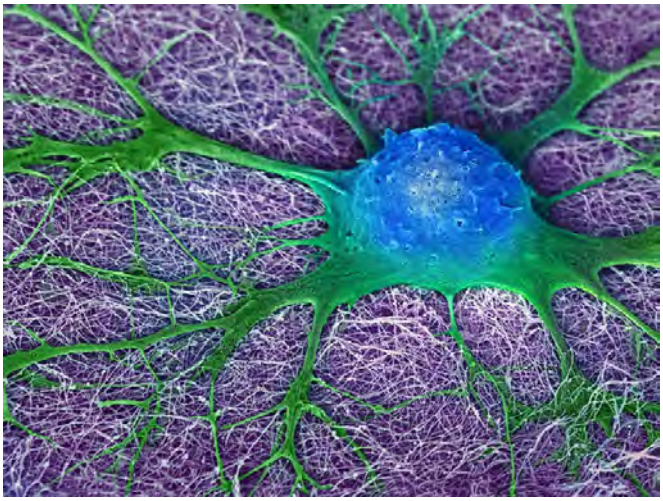
While developing effective treatments is crucial, early diagnosis of ADRDs is equally important in managing the disease. The current diagnostic pathway for AD is often slow and outdated, relying on technology developed decades ago. This creates bottlenecks, particularly at the point of specialist referral, where long wait times can delay diagnosis.

Recognizing this, TauRx has collaborated with Genting Berhad Malaysia to establish GT Diagnostics, with the vision of transforming the diagnostic landscape and market for dementia.[386] GT Diagnostics is focused on developing much-needed tools that support early diagnosis and monitoring of dementia's progression. These patented digital tools are designed to be accessible and readily deployable, ranging from home-based well-being apps to professional tools for experts.[387] By making these tools available through various service providers—including financial and professional services, personal advice and support, residential and non-residential care, and specialized dementia centers—GT Diagnostics aim to bring dementia diagnostics into the 21st century, enabling timely intervention and better disease management.

As the global burden of ADRDs is projected to reach 78 million by 2030 and 139 million by 2050, the importance of innovation in treatment and diagnosis cannot be overstated.[388] TauRx Pharmaceuticals is at the forefront of this effort, leveraging its strong intellectual property portfolio to protect groundbreaking therapies like HMTM. Its focus on improving diagnostic tools promises to enhance the speed and accuracy of diagnosis, ensuring that innovative treatments can be administered earlier and more effectively, ultimately improving patient outcomes.

Asma Saeed Al-Amoodi Innovates Stem Cell Treatments for Leukemia

By Mohammed Suleiman



Cancer is notoriously difficult to treat, and leukemia is no exception. Researchers around the world work tirelessly to develop more effective treatments, and stem cell research is one avenue that holds the greatest promise. Saudi Arabian researcher Asma Saeed Al-Amoodi has made some key breakthroughs in the use of blood stem cells to combat leukemia.

Studies estimate that 2020 saw a total of 474,519 new leukemia cases, with a reported global rate of incidence at 5.4 per 100,000 people.[389] The mortality rates reported that year reached a total of 311,594 deaths, with Western Asia having the lowest rate around 4.6 per 100,000 people while North America had the highest rate at around 10.9 per 100,000.

In Saudi Arabia the incidence rate reflected the global average, staying around 5.4 per 100,000, and the mortality rate sat somewhere between 3.7 and 4.2 per 100,000. The disease poses a substantial health problem for the country, being the fifth-most-common disease in 2017 regardless of age or sex.[390]

Drug shortages are a massive problem worldwide and present a particular obstacle to cancer treatment. A 2020 study analyzing responses from 55 Saudi Arabian healthcare professionals across nine major oncological institutions showed that every single one reported that drug shortages interfered with their work.[391] With each of the nine institutions averaging 640 cancer patients per year, one-third of those patients experienced decreased quality of life or lost faith in the institution because of drug shortages.

Research breakthroughs by scientists like Asma Saeed Al-Amoodi help to relieve treatment shortages.[392] During her tenure as a Ph.D. student at the King Abdullah University of Science and Technology (KAUST), Al-Amoodi developed a set of tools to improve the efficacy of hematopoietic (blood-specific) stem cells in bone marrow transplants by augmenting the ability of blood stem cells to target affected areas in the body and graft to them.

Al-Amoodi's patents, "Methods of producing enzymes using Pichia cells," and "Compositions and methods for preparing CD34NEG stem cells for transplant," cover the innovations she has made in improving bone marrow transplants.[393] The former indicates a method of producing key enzymes with a *Pichia pastoris* yeast culture, the latter an improvement on the preparation of transplantable material, and both patents illustrate the value of Al-Amoodi's contribution to global healthcare.

Even a successful bone marrow transplant does not guarantee that the new blood stem cells will properly attach to the host marrow, which is necessary for them to start producing healthy blood cells. Previous techniques struggled to ensure proper grafting, but Al-Amoodi's research offers a substantial improvement.[394]

Al-Amoodi's patents garnered her high praise, including the L'Oreal-UNESCO For Women in Science Middle East Fellowship in 2019 and the *MIT Technology Review* Innovators under 35 award for the Middle East and North Africa region in 2022.[395] The L'Oreal-UNESCO award is given to recognize and highlight the contributions of female researchers. Al-Amoodi received the award for her work in "enhancing the use of certain stem cells for the treatment of hematological diseases like leukemia" and she has stated that receiving these awards turned her dreams of helping society into a reality.

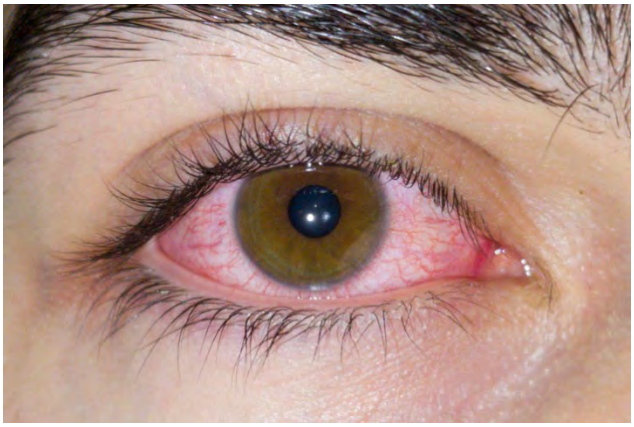
UNESCO teaches the L'Oreal-UNESCO award winners how to share their inventions with the world. As part of the program, officials from the World Intellectual Property Organization (WIPO) provided a course in 2022 to teach these inventors about their IP rights.[396] Intellectual property (IP) protections and education on the subject are crucial especially for young inventors who are unsure of their options and rights and foundations such as WIPO enable inventors like Al-Amoodi to protect their inventions, secure funding to fully realize them, and share them with the world.

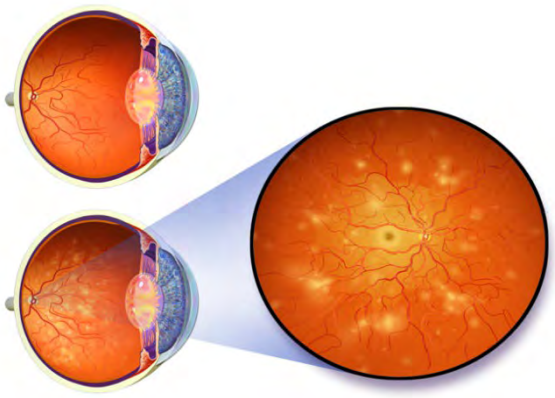
Intellectual property is vital for innovators like Al-Amoodi in the healthcare industry. Without IP protections, inventors would not be able to secure their inventions and may decide to hold onto lifesaving treatments in fear that their work might be stolen. Indeed, IP rights are critical in ensuring that innovations are not commercialized without their inventors' consent and enabling those inventors to secure the funding necessary to fully develop their ideas.

Without IP, inventors like Al-Amoodi would have much more difficulty funding the research processes necessary for innovation. Without protections like patents, progress and innovations in every industry would slow to a crawl without creative minds constantly working to make the world a better place. IP allows inventors like Al-Amoodi to make breakthroughs that were previously thought to be impossible, and with her patents Al-Amoodi is more likely to secure the resources she needs to bring new, lifesaving treatments to the world.

Beyond What Meets the Eye: How SELENA+ is Revolutionizing the Detection of Eye Diseases

By Natalie Khoo





Diabetes is a chronic, progressive metabolic disorder characterized by elevated levels of blood glucose or blood sugar.[397] This occurs when the pancreas fails to produce enough insulin—a hormone essential for regulating blood sugar—or when the body becomes unable to effectively use the insulin it produces.

Currently, 422 million people worldwide have diabetes, a figure that is expected to grow to approximately 643 million by 2030 and 783 million by 2045.[398] In 2019, diabetes was the direct cause of 1.5 million deaths, with 48 percent of these deaths occurring before the age of 70, underscoring the disease's severe impact on life expectancy.[399] Equally alarming is the rise in young-onset diabetes as more children and adolescents are being diagnosed with childhood obesity due to factors such as poor diet and physical inactivity.

Both the United Nations (UN) and the World Health Organization have identified diabetes as a major global health concern due to the increasing prevalence and significant economic burden it places on individuals, families, and healthcare systems, particularly in low-and-middle income countries.[400] The rising cost of managing diabetes, especially with the growing reliance on expensive analogue insulins, contributes to substantial financial strain, often outpacing the benefits of more affordable treatment options. This economic impact extends beyond medical expenses, as people with diabetes also face loss of productivity, income, and quality of life.

Moreover, diabetes can lead to a wide range of serious health complications that can significantly affect and impair an individual's quality of life. Among this is diabetic retinopathy, a condition where high blood sugar levels cause damage to the retina's blood vessels.[401] Diabetic retinopathy affects nearly one-third of people with diabetes and is a leading cause of vision impairment and blindness globally. While long-term vision loss can be prevented by early detection and treatment, many healthcare systems are not adequately resourced or lack trained professionals to conduct the necessary screenings.[402]

In response to the growing challenge of diabetic retinopathy, innovative technologies like SELENA+ (Singapore Eye Lesion Analyzer) are increasingly playing a role in streamlining and enhancing healthcare delivery.[403] SELENA+ is a patented deep-learning AI software system that is designed to detect potential threatening eye conditions accurately and efficiently.[404] Developed through a collaboration between Singapore Health Services and the National University of Singapore (NUS), SELENA+ utilizes excellent image processing algorithms to analyze retinal images and detect early signs of diabetic retinopathy, glaucoma, and age-related macular degeneration.[405]

Similarly, unlike traditional screening methods, which are time-consuming, resource intensive, and highly dependent on the expertise of human graders, the software leverages convolutional neural networks along with a deep learning system to process and interpret retinal images with remarkable precision. Additionally, the strength of SELENA+ lies in its ability to mimic human intelligence, identifying complex patterns and structures in retinal images.[406] Through extensive training on datasets of nearly 500,000 retinal images from multi-ethnic populations across various countries, SELENA+ has demonstrated an ability to match or surpass human graders in detecting retinal abnormalities.[407]

Furthermore, this innovative approach has been integrated into Singapore's Integrated Diabetic Retinopathy Programme, leading to a 50 percent reduction in workload for clinicians.[408] Results are available in minutes, instead of the hours or days typically required by traditional methods, optimizing healthcare resources, and enabling more timely and personalized care plans for diabetic patients. With the number of diabetic patients in Singapore expected to double by 2050, SELENA+ offers a promising solution to alleviate the growing burden on healthcare systems.[409]

Moreover, the commercial success of SELENA+ has been largely attributed to the strong intellectual property protections that underpin its development and commercialization. By securing patents such as US20200211235, WO2019022663, SG11201912260, the developers maintain exclusive rights to their innovation, thereby ensuring not only the local deployment of this AI-driven retinal diagnostic tool but also its global commercialization through EyRIS, a startup focused on introducing this AI-driven retinal diagnostic tool to international markets.[410]

Besides, the role of intellectual property in this context extends beyond mere legal protection; it has been a key driver for innovation, attracting significant investment and facilitating the adoption of cutting-edge healthcare technologies like SELENA+ across healthcare systems worldwide.

As SELENA+ continues to evolve, its future applications could extend beyond eye health, positioning it as a comprehensive tool in preventative healthcare. The developers are exploring its potential to assess cardiovascular risks by analyzing biomarkers found in retinal images.[411] Changes in the blood vessels of the retina, for instance, can reveal early signs of cardiovascular issues, providing critical insights into a patient's overall health. This capability could significantly aid in early detection of heart disease, stroke, and other related conditions, transforming SELENA+ from a specialized diagnostic tool into a broader platform for chronic disease management.

Moving forward, the success of SELENA+ exemplifies how intellectual property serves as a catalyst for innovation in the healthcare industry. Its development reflects Singapore's broader institutional strengths, particularly its well-established intellectual property framework. As a resource-limited city-state, Singapore has strategically invested in strong institutional foundations to drive economic growth and technological

innovation. The country's commitment to intellectual property protection plays a central role in this strategy, enabling Singapore to safeguard its technological advancements and maintain a competitive edge in global markets. SELENA+ stands as a testament to how robust intellectual property frameworks can propel technological breakthroughs and foster innovation, particularly in high-impact fields like healthcare.

Conclusion

Moving forward, the 26 case studies presented in the Innovate4Health project elucidate a powerful truth: innovation, particularly when supported by robust intellectual property rights, plays an essential role in meeting global health challenges and improving public health. From Argentina to Uganda, India to Egypt, these innovators have developed creative solutions to some of the world's most-pressing health challenges. These innovations aren't just improving existing treatments, but are fundamentally reshaping how healthcare can be delivered, especially in resource-constrained environments. By recognizing the significance of robust intellectual property rights in protecting and promoting these innovations, we can help ensure that pioneering solutions continue to flourish, reach those who need them most, and inspire further advancements.

Moreover, central to each case study is that effective healthcare innovation often happens closest to the point of need. Whether it's SerenOx's groundbreaking diagnostic services in Tanzania or InCurA's innovative wound healing technology in Egypt, these innovations demonstrate the value of supporting local ingenuity. As we face a future of evolving health challenges, these innovators remind us that the future of global health lies not in a one-size-fits-all approach, but in fostering an ecosystem where innovators worldwide can develop and implement solutions tailored to their local contexts.

Collectively, the case studies here tell a compelling and inspiring story of how entrepreneurs are creating IP-enabled life-sciences innovations to tackle some of the world's most-significant health challenges. Innovate4Health stands as a testament to the important role intellectual property rights play in driving life-sciences innovation worldwide.

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