EDITORIAL: Covid-Vaccine Patent Waiver: Will it Increase Worldwide Access?

June 2021

Now that millions of people have received one or two shots of vaccine, we tend to forget that such astounding vaccine efficacy, distributed via an incredible supply chain around the world, was achieved in less than 12 months.

There is some legitimacy in considering that Covid-vaccine intellectual properties may belong to humanity. After all, several governments, led by the US, spent billions of dollars in either funding some of these companies and/or preordering at risk, in order to pursue parallel-path development and large-scale manufacturing, also at risk. The common belief is that, by waiving the patent ownership, Covid vaccines could be available more quickly in poor countries at lower cost, that pharma companies should make no profit on this product, and finally, that solidarity should prevail for the benefit of mankind.

The above rhetoric, unfortunately, forgets one key parameter in the whole equation: without private corporate initiatives, financed by shareholders' money expecting a return, extraordinary initiatives taken by entrepreneurs, huge at-risk investment in manufacturing long before Covid-19 popped up, these vaccines would certainly not be available today.

Indeed, few pharma companies have been working on mRNA for many years, prior to the current crisis, and spent hundreds of millions in shareholders' money to develop this technology. This is clearly the case for Moderna and BioNtech, which were ready to switch some of their internal programs to Covid vaccines almost overnight, back in late December 2019. This was done expeditiously, at risk for them, and before government funding. Without these prior shareholder investments, we would not enjoy today hundreds of millions of vaccinated people around the world.

The immediate impact of a patent waiver for Covid-vaccines is likely to be mitigated by several factors. Beyond the patent itself, vaccine companies have developed an internal know-how that is key for successful manufacturing. The leading Covid-vaccine makers publicly have already said that they refuse to share that proprietary information in a case of patent waiver. In addition, the disruption of the supply chain is likely to cause manufacturing delays for the vaccine originator.

The solution is rather to entice existing vaccine manufacturers to scale up already approved facilities, combined with government direction of portions of these productions to developing countries at an affordable price. One example, although not well executed so far, is the deal AstraZeneca signed with the Serum Institute of India (ISS) to gain rights to manufacture locally in India, a lower-cost Covid vaccine for developing countries, including India, paying token royalties, under license agreement[1].

Intellectual property is the backbone of the pharma industry. It must stay in order to provide certainty to investors that fair returns will be made to their investments. We are confident that objectives laid out by governments to make health products available to the world's poorest countries can be achieved without impacting the patent system.

Alain Gilbert
Venture Partner

[1] AstraZeneca (Jan 6 2021) https://www.astrazeneca.com/media-centre/press-releases/2021/serum-institute-of-india-obtains-emergency-use-authorisation-in-india-for-astrazenecas-covid-19-vaccine.html

RECENT NEWS

Apr'21 Atea announced the first patent was dosed in the Phase 3 MORNINGSKY trial, a global multicenter study evaluating AT-527 in mild or moderate outpatients with COVID-19. The trial is expected to enroll approximately 1400 non-hospitalized adults and adolescents with mild-to-moderate COVID-19. AT-527 is an orally administered, direct-acting antiviral in development and derived from Atea's purine nucleotide prodrug platform. Under a strategic collaboration, Roche and Atea are jointly developing AT-527 for the treatment of COVID-19.

www.ateapharma.com

May'21 Checkmate began patient dosing in a Phase 2 trial assessing the efficacy and safety of vidutolimod (CMP-001) combined with nivolumab for the treatment of advanced-melanoma patients refractory to anti-PD-1 therapy. The company previously announced the launch of a different trial comparing the efficacy and safety of the vidutolimod/nivolumab pairing with nivolumab monotherapy in patients with first-line metastatic or unresectable melanoma. The data from these two trials will be used to support a Biologics License Application for the treatment of patients with anti-PD-1 refractory advanced melanoma.

www.checkmatepharma.com

May'21 eFFECTOR and Locust Walk Acquisition Corp. (NASDAQ: LWAC), a blank-check company formed for the purpose of acquiring or merging with one or more businesses, announced a definitive merger agreement. When the transaction closes, which is anticipated to occur during Q3 2021, the combined company will be named eFFECTOR Therapeutics, Inc., and will be led by Steve Worland, PhD., president and CEO. The combined company's common stock is expected to be listed on the Nasdaq Capital Market under the ticker symbol "EFTR." Gross proceeds are expected to include USD60m from a committed PIPE (Private Investment in Public Equity) and up to USD175m held in trust.

www.effector.com/

May'21 Prilenia announced that it has now enrolled more than 120 patients in its Phase 3 trial of pridopidine in Huntington's disease (PROOF-HD), which bring the study to 25% of the total enrollment. The study remains on track to complete enrollment by Q4 2021. The study is being conducted in collaboration with the Huntington Study Group at 60 sites across North America and Europe. To date, no safety signals of concern have emerged, and none of the participants has dropped out from the study. These findings are consistent with the established favorable tolerability and safety profiles of pridopidine.

www.prilenia.com/

COMPANY FOCUS: EDGe Surgical

Q&A with Christopher Wilson

President and CEO

What Prompted You to Co-Found EDGe Surgical and Assume the Role of CEO?

I have long been active in product development, corporate strategy, and mergers & acquisitions in the medical-device arena, so my interest in EDGe Surgical was a natural next step. It definitely suits my entrepreneurial career objectives and capabilities. Another attraction for me was the access it provided to disruptive and value-driven orthopedic and spinal medical technologies created and designed by prominent surgeons, which should offer the company a novel product-driven advantage in the marketplace. To this end, we have been able to assemble a well-respected and established team, including our advisory board, to enable EDGe Surgical to effectively execute our vision. It is also worth noting that, even though I concentrated in entrepreneurial studies in business school, that subject is not something one can truly learn in the classroom or from books. You want to be an entrepreneur? Start a company! Along with my co-founders KC Hoos and Tyler Wanke, we created EDGe Surgical to transcend outdated orthopedic instrumentation by creating new tools that have the potential to improve the efficacy and safety of surgical procedures. That was our vision. The rest is, as they say, history.

What are the Key Selling Points of the Ortho EDG® Depth Gauge?

The patent-protected technology incorporated into the Ortho EDG® depth gauge sets a new standard-of-care in orthopedic surgery through two core features: first, it improves accuracy in the selection of screws to fuse bone fractures, and, second, it mitigates the risk of bioburden contamination, a leading cause of surgical-site infections. In so doing, the Ortho EDG® depth gauge has been shown to improve surgical outcomes, enhance the patient's experience, and reduce costs.

What are the Next Steps and Milestones for EDGe Surgical? Where Will the Company Be in Twelve Months?

Over the next year, we have two key milestones to meet. The first is to drive sales of our Ortho EDG® device, which has already received 510(k) clearance from the US Food and Drug Administration and CE certification from the European Union, and the second to obtain FDA 510(k) clearance of our next-generation device for the spine market, the Awl-in-One Tap™. All in all, the current moment has been exciting for EDGe Surgical, and we are very optimistic about the future.

Sectoral invested in EDGe Surgical in 2020.

ABOUT PRIVATE INVESTMENTS AT SECTORAL

Founded in 2000, Sectoral Asset Management Inc. is one of industry-leading specialist in managing global investment portfolios in the healthcare sector. Sectoral's first private equity investments were made by allocating assets from our small-cap funds. Since then, we have built on our early successes, backing innovative private companies, and launched the first dedicated fund to private companies in 2015. Investment focus is maintained on late-stage development for drugs and medical technologies addressing significant markets and having high potential for approval. We leverage Sectoral's established healthcare expertise and capabilities across public- and private-company investments to capture meaningful value creation for our investors.

INVESTMENT TEAM

Michael Sjöström, CFA
Senior Partner
Co-founded Sectoral in 2000

Marc-André Marcotte, CFA
Partner
Joined Sectoral in 2006

Stefan Larson, Ph.D.
Partner
Joined Sectoral in 2018

Alain Gilbert
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Sectoral advisor since 2015

Howard Riback, CPA, CA
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François Beaubien, Ph.D., CFA
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Joined Sectoral in 2014

Catherine Poulin-Filion
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