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March 15th, 2024

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Hope everyone had a good President's Day weekend. The elections have dominated the news where Presidential candidates are trying to win votes by addressing the issues that the American people are most concerned about such as the economy, the border control, the war in Gaza etc.

In doing so, one of the things that has been flying under the radar with the general public is [President Biden's proposal](#) in early December 2023 "to seize the patents of certain costly medications in an effort..... to slash high drug prices and promote more competition in the pharmaceutical industry in the U.S." A controversial policy known as "**march-in rights.**" The public has 60 days to voice their opinion.

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If you missed last month's newsletter on "Can Donald Trump Legally Run for the 2024 Elections: Three Big Legal Questions?" Click [here](#) to read the article.

If you need a little inspiration or something to make us laugh to get us through this difficult time, click on the "[Inspiration](#)" link to give yourself a few minutes to relax and enjoy the music from the Berklee School of Music in their song "What the World Needs Now," and ending with Celine Dion and Josh Groban with "The Prayer".

Please read on for other current news in the Table of Content below. The next newsletter will be April 15, 2024.

We encourage you to share this newsletter with your colleagues by using the social media icons below, or by simply forwarding this newsletter or use the link below. Should you or your colleagues want to join my mailing list, click on "join my email list" link below.



Sincerely,
Regina Au
CEO, New Product Planning/Strategic Planning
[BioMarketing Insight](#)



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Developing a Product? Commercializing a Product?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact [me](#) for an appointment. For successful commercial adoption of your product or looking to grow your business, contact [me](#) for an appointment.

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[Scenario Planning](#) - for more information, email [me](#).

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3rd Annual International Vaccine Congress (IVC 2023) Conference on October 23-25, 2023 in Woburn, MA

I am pleased to announce that I spoke at the IVC 2023 Conference in Woburn, MA on October 23 - 25, 2023. The title of my presentation is "Lessons Learned from the Covid - 19 Vaccine and What is Needed When Developing a Vaccine for a Successful Rollout". For more information on my presentation, click [here](#). For more information on the conference, click [here](#).

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Recap of the AAPI Heritage Festival - Saturday, May 20th, 2023

The Asian American Pacific Islander (AAPI) Heritage Festival was a success in celebrating AAPI Heritage Month with both the Asian and nonAsian communities. This celebration was to build awareness and educate our community on the various cultures and contributions the different Asian and Pacific Islanders ethnic groups have brought to enrich our American History.

Our Festival made the front page of the Daily Times Chronicle. See the article and pictures of our speakers, musicians and performers. In addition, we had our "Contributions AAPI Have Made to American History" Exhibit on display in the lobby and continued on into the program room. More pictures will be revealed next month.

Guest Speakers: Massachusetts State Representative Vanna Howard
Mayor Scott Galvin of Woburn

Special Guest Musician: Kevin So

Guest Musician: Entian Lee, Chinese Zither

Guest Performers: Swasti Bhargava & Aanvi Bhargava, Ekam Boston
Anvee Gudipati, Sreshta Mahavadi, Ekam Boston

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City Council seeks more info on fill

By PATRICK BLAIS

WOBURN - The City Council wants to consult with the city engineer's office and other department head managers before allowing a Lowell Street landowner to spread out fill in a low-lying depression.

During the elected officials' latest gathering in City

Hall, Boxford resident Valentino Tocci Jr. explained that he is looking to bring in more than 100 cubic yards of fill to the back yard of a two-family property at 2 Lowell St., which sits in the city's Central Square area by Main Street.

The council, looking for additional details about the total volume of soil and rocks being brought in and

Lowell St

how the work will impact the site, ultimately after 6 meetings.

According to Town nearby professional engineers, the proximate .61-acre site towards that corner towards Cummings reportedly does not have the topography of the significant storm event.

"This is mostly an unsightly area. Other work in that area and may be explained.

"We would then still accept rainwater runoff," he continued, likely also be planned.

Since the special month, both Assistant and Planning Director the council cited the water storage volume situation on abutting.

In order to be selected doesn't create experts recommending firm to consult.

"There is no other shape, other than soil. Depending on remain in this lot," Rheume noted.



THE ASIAN AMERICAN PACIFIC ISLANDERS HERITAGE FESTIVAL was held at the Woburn Public Library with many posters describing the contributions made to American history. Volunteers and participants in the AAPI Heritage Festival included (l-r) Katherine Jiao, Vicky Wu, AAPIEC Inc. President Regina Au, and Ekam USA-Boston Chapter Director Nagasree Chakka. Some of the entertainment were dancers and musicians inside the library along with food vendors set up outside in the library's parking lot. (KAPAndrewsPhotos)

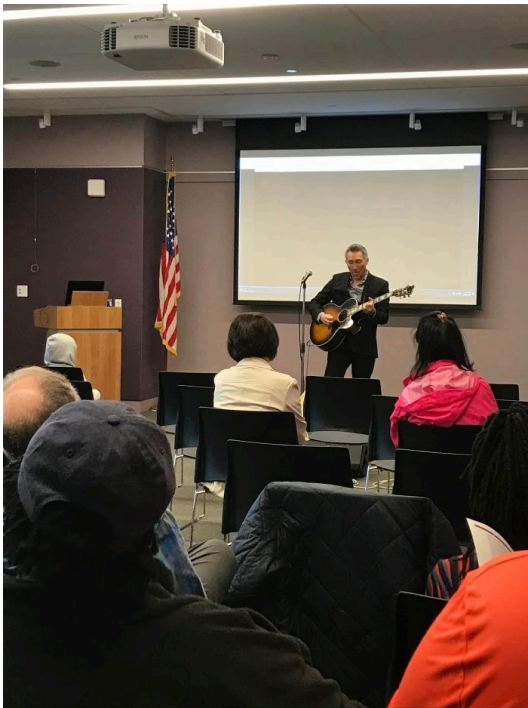
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Inspirations

Enjoy the song "What the World Needs Now" virtually with the students from the Berklee School of Music.

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Practice Good Hygiene Every Day.



Let's End with Celine Dion & Josh Groban Singing "The Prayer"

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One Biotech Executive's View on the COVID-19 Vaccine

I am pleased to announce that my article on the COVID-19 Vaccine was published in Lioness Magazine. To read my article click on the link [here](#).

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Should the Government Seize Patents for Certain Costly Medications, a Policy Know as the March-in Rights?

Source: CNBC, President Joe Biden speaks about protecting Social Security, Medicare, and lowering prescription drug costs, during a visit to OB Johnson Park and Community Center, in Hallandale Beach, Florida, on Nov. 1, 2022.

In March 2023, the [HHS and DOC](#) Announce Plan to Review March-In Authority as laid out in the [Bayh-Dole Act](#) of 1980, which promotes commercialization of research results, maximizes the potential for federally-funded technologies to become products, and serves the broader interest of the American public.

“The Biden-Harris Administration is committed to increasing access to health care and lowering costs. And march-in authority is a powerful tool designed to ensure that the benefits of the American taxpayer’s investment in research and development are reasonably accessible to the public,” said HHS Secretary [Xavier Becerra](#). “We look forward to updates from the Bayh-Dole Interagency Working Group, and at my direction, HHS will review the findings, engage the public, and better define how HHS could effectively utilize our authority moving forward.”

In [December 2023](#), the Biden Administration announced and proposed to seize drug patents in a move to slash high prices. The [new framework](#) of the Bayh-Dole act will take patents for drugs developed with taxpayer funds and share them with other pharmaceutical companies if the public cannot “reasonably” access the medications. Doing so could lead to the development of lower-priced generic alternatives, which could cut into key drug companies’ profits and reduce costs for patients.

Former Sens. Birch Bayh (D-Ind.) and Bob Dole (R-Kan.) in 2002 [wrote to the Washington Post](#) that the 1980 law they co-authored [wasn’t meant for the government to set prices](#).

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the Bayh-Dole Act of 1980, a senior administration official said.

The proposal is open to the public's feedback for 60 days.

[In response to this proposal](#), the pharmaceutical industry, Trump and Obama administration officials, and others are urging the Biden administration to reconsider a controversial plan for seizing patents on a drug when its cost gets too high, claiming the approach misinterprets decades-old law and threatens the delicate pipeline that produces innovative, life-saving drugs.

Over 500 comments were filed by the Feb. 6 deadline for groups and individuals to weigh in on the Biden [administration's framework](#) for the federal government to use its march-in rights. The proposal lays out the Biden administration's stance in a longstanding debate over whether price is a justifiable reason for the government to "march in" and take over a patent on technology developed with the help of taxpayer dollars and then license it to an outside manufacturer.

The Biden plan is already drawing blow back from a broad swath of players in the innovation space. A collection of former US Patent and Trademark Office directors and other government officials under the George W. Bush, Obama, and Trump administrations [wrote to warn](#) that the proposed framework, if adopted, would prove destabilizing.

The Pharmaceutical Research and Manufacturers of America likewise is urging the administration to [pump the breaks](#), calling the plan a misinterpretation of the Bayh-Dole Act, which established march-in rights.

"The proposed framework sounds politically sexy—grab patents of companies if their drug prices are too high. But the impact will disappoint consumers—even the most aggressive efforts to reinterpret march-in rights would not affect 99 percent of drugs," the Council for Affordable Health Coverage [wrote](#).

"While the Biden Administration talks tough, its approach will simply chill investment in new treatments and cures because the threat of the government stealing patents hangs over every new idea's success," the council said.

In addition, on March 5, 2024, U.S. Senator [Shelley Moore Capito](#) (R-W.Va.), Ranking Member of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (Labor-HHS), joined a group of 16 of her Republican colleagues to send a letter raising serious concerns to National Institutes of Health (NIH) Director Monica Bertagnolli, M.D. following President Biden's [proposal](#) that attempts to allow agencies to seize drug patents under the *Bayh-Dole Act* if the

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This effort was led by U.S. Senator Bill Cassidy M.D. (R-La.), Ranking Member of the Senate Health, Education, Labor, and Pensions (HELP) Committee. The senators expressed concerns that if the agency illegally uses “march-in” rights, it will severely hamper health care innovation and deny millions of Americans future lifesaving cures and treatments.

“A short-sighted decision to exercise march-in rights would work against your stated goal and jeopardize patient access by discouraging individuals from partnering with NIH to develop new cures and treatments,” [the senators wrote](#). “Not only will this hurt patients, but it will also diminish the return the public gets on the investments Congress makes in NIH each year – something we should all seek to optimize.”

“We share the bipartisan goal of wanting to lower drug prices for American patients and families. But using march-in rights to address drug prices would do more harm than good,” [the senators continued](#). “Agencies, including NIH, should not abuse their authorities to illegally seize intellectual property, and in the process jeopardize the valuable public-private partnerships that make our biomedical research enterprise the best in the world.”

What is your opinion? See my closing thoughts.

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Closing Thoughts

Bring down the cost of drugs for patients/consumers is ideal, but most people don't understand how pricing works particularly in the drug and medical device industry. People have targeted the manufacturer to bring the cost down. But the manufacturer is the beginning of the pricing structure and not the end. After the manufacturer, the pricing

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Insurance companies negotiate with the manufacturers for a lower price if the manufacturer wants to have their product on the insurance company's formulary list so that the physicians don't have to write a Prior Authorization (PA) in order for the patient to have access to that drug. Obtaining a PA is time consuming and there is no guarantee the drug/device will get approved.

Even if the PA is approved the patient will pay a higher copay (co-pays have 5 tiers with tier 1 being the lowest for generics) and in this case Tier 4 for non-formulary name brand medication. It's complicated and every insurance/payer has their own formulary and co-pay structure.

When a patent is taken from the manufacturer as proposed by the Bayh-Dole Act, one is affecting the livelihood of the company. Without a patent, a company can't survive. The reason the patent life is for 20 years, is to recoup their R&D cost, allocate money to develop new drug/device programs, pay their employees etc. as every company is a business. But in life sciences, the manufacturer's goal is to develop life saving drugs/devices.

In addition, public companies need to satisfy their shareholders who expect the company to make a lot of money, so the stock goes up and the companies can pay out dividends to their shareholders. For private companies, they need to satisfy their investors otherwise they won't receive additional funding to continue developing their product particularly in the early stages of product development.

If the government can seize a patent at any time, this is a strong disincentive for companies to develop products. A good example would be the antibiotic market. Due to bacteria developing resistant to an antibiotic so rapid, could be five, 10 years, depending on usage, then the drug is no longer used despite a 20 year patent protection. Which translates to at least 10 years of no revenue.

This is the main reason why so many companies have exited the antibiotic market. They are definitely not getting their return on investment (ROI) which they just spent a minimum of \$1 billion dollars to bring their product to market. Even incentives from the government for companies to develop antibiotics have not drawn companies back to this market. These incentives have been offered twice. The same thing will happen if the government seized a patent before the expiration date.

In India, a developing country, the government will seize a patent from foreign companies and allow local companies to manufacture it for products that are needed by their people. India's healthcare system is mainly [universal healthcare](#) with a few private systems.

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employment. You can understand why the government seizes patents, but the government is also not getting the innovative drugs that is needed by their people.

Although many companies were focused on emerging markets such as Brazil, Russia, India, China, South Africa (BRICS) for growth and opportunity, many companies have pulled back because of language, culture and business challenges in entering the BRICS market.

The bottom line is that Biden's current proposal should be withdrawn and go back to the drawing board for another method of bringing the cost of medications down. This issue is not a quick fix as the system for the hospital, physicians, manufacturer, payers etc. is very complex and intertwine between all the them. What affects one will affect the others and more as one peels back each layers.

The industry has been trying to find a solution for years, but as they understand one part of the healthcare system for what they are trying to accomplish the more complicated it gets because they find they have to fix/consider more things to make it work. It's similar to going down a rabbit hole.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition, target product profile and economic value of your product for reimbursement, feel free to contact me at 617-404-8826 or regina@biomarketinginsight.com.

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