Directors & Officers: Biotech Protect

INIGO

Chasing ‘Blockbuster’ Status:

The Impact on Securities Class Actions

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Litigation against pharmaceutical companies is not new. Nor is the frequency of securities class action (SCA) filings against these companies over the past 10 years. In 2024, one in every five SCAs filed was against a pharmaceutical company.

That's perhaps no surprise. The pharmaceutical industry is one of the most heavily regulated, and has been the subject of many high profile scandals.

For smaller biotech companies, they set out with the hope of curing a particular disease, only for it to fail in clinical trials. Often, after years of work and positive results, these companies fall at the last hurdle of approval from the US Food and Drug Administration (FDA). For public companies, this failure often ends in a stock drop and resulting SCA filing from shareholders.

The uncertain macro-economic climate these companies find themselves in has similarly been a source of claims activity. Of 700 publicly traded biotech companies, over 200 are currently carrying negative equity, a signal from investors that these companies are almost worthless as their shares are collectively trading at a discount to their cash balance.

However, another reason has emerged over the past five years for why so many SCAs have been filed against pharmaceutical companies.

Releasing a blockbuster drug – defined as generating annual sales of $1bn or more – is every pharma company's dream. Most times, that's all it remains. The odds of a drug even being approved by the FDA are slim. In 2024, it gave the green light to 50 new drugs, either as new molecular entities (NMEs) or as new therapeutic biologics. That sounds like a healthy number, but to put it in context, over 515,000 global clinical trials were registered last year.

So, if getting regulatory approval is the pharmaceutical equivalent of hitting the jackpot, the chances of creating a blockbuster drug, are even slimmer. Then, the race is on among your rivals to come up with an alternative. In reality, that racetrack is littered with losers, illustrated by the number of SCAs filed against drugmakers.

The success – and failure – of drugmakers to make blockbuster drugs in treating cancer and Covid-19, we believe offers an indication of where the next hotspot will be in pharma litigation.

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Cancer

The number of people who have cancer is forecast to rise dramatically in the next 25 years, with as many as 12m new cases a year by 2050, pushing the total to around 32m.

The search is on for new cancer medicines to tackle the growing problem, with global spending on cancer medicine set to jump by over 80% between 2023 and 2028, to reach $409bn[1].

In 2023, the number one blockbuster drug worldwide was Merck's Keytruda, which generated more than $25bn in revenue[2]. Keytruda is a type of immunotherapy that blocks the PD-1 pathway to help the immune system detect and destruct cancer cells, which can be used to treat 20 different types of cancer.

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While cancer is an umbrella term for so many types of disease, this therapeutic area is among the most competitive. The opportunity to take even 1% of Keytruda's market share surely inspires many clinical stage biotech companies to roll the dice. It seems to be this gamble, that has led publicly listed pharmaceutical companies with cancer candidates to be responsible for 17% of the 205 SCAs filed against pharma companies over the past 5 years.

Most recently, Merck's competitors have essentially given up on developing a rival to Keytruda, and have instead switched tact to boost their chances of success. As they say, if you can't beat them, join them. Rival pharma companies are now working with Merck in collaboration to evaluate the effectiveness of their novel compounds in combination with Keytruda. Lilly first announced their collaboration agreement in 2015 and since then many have followed suit including Gilead in 2022, Moderna in 2023, Exelixis and Prelude Therapeutics last year to name a few.

According to the National Cancer Institute, there are currently 478 clinical trials that are studying pembrolizumab.

Whether this helps to temper the SCA frequency against pharma companies remains to be seen, but it is certainly the latest route to success in the cancer space.

Covid-19

After cancer, the second-most frequently sued public drug companies were those looking to create Covid-19 drugs.

The world was brought to a halt in 2020 by the Covid-19 global pandemic, which saw over 211m people diagnosed with the virus worldwide by August 2021[3].

As countries across the globe were forced into a succession of lockdowns, the race was on to find Covid-19 treatments. In 2021 it was expected that Covid-19 spending alone would contribute $157bn to the pharmaceutical market by 2025[4].

At the peak of the outbreak in July 2020, there were 150 Covid-19 vaccine candidates in development. Overall, the World Health Organisation reports there has been a total of 382 global Covid-19 vaccine candidates[5], but only two became blockbusters: Pfizer and BioNTech's Comirnaty and Moderna's Spikevax.

Just as with Merck's rivals attempts to develop an alternative to Keytruda in cancer treatment, other drug companies raced to create blockbuster Covid-19 treatments to compete with Comirnaty and Spikevax. But their inability to create effective vaccines often resulted in investor lawsuits. One in ten SCAs filed against US-listed pharma companies since 2020 has been because of the failure of their Covid medicines.

A key reason for the number of class actions in this space, was the rushed development process for Covid-19 vaccines. A typical timeline for vaccine development takes 10-15 years on average, but Covid-19 vaccines that were authorised for use in the US had a reduced timeline of 10-18 months.

This haste to find a solution is revealed in many of the SCA complaints. Novavax, Inc. was sued by shareholders for failing to meet its Emergency Use Authorisation regulatory timeline, while NRx Pharmaceuticals, Inc.'s unsuccessful application, due to insufficient data, also meant it received a lawsuit from its investors. The success of Cominarty and SpikeVax meant there was no point in other drugmakers refining the development of their own medicines. The race to become a blockbuster had therefore been lost, and the pandemic had receded. Unfortunately, the price of failure for these pharma companies was often a SCA.

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So where could the next litigation hotspot be?

Obesity drugs could be the blockbusters to beat all blockbusters. The market leader, Novo Nordisk's semaglutide, sold as Ozempic or Wegovy, has not only turned the pharma business on its head, it has also wrought changes across the fitness, food and drink industries.

In 2023, it is estimated that there were 20 million Ozempic prescriptions in the US, a growth of more than 5,000% since its original release in 2018[6]. But the market for obesity drugs is expected to get bigger. Much bigger. It could grow more than 15-fold by 2030, from $6 billion in 2023 to over $100 billion in 2030. By 2035, up to 9% of the US population may be taking the drugs[7].

We recently saw Roche sign the biggest obesity drug deal yet with a $5.2bn licensing agreement from Zealand Pharma[8].

With demand for these weight loss pills set to be turbocharged, it's no wonder drugmakers are scrambling to develop their own obesity blockbuster. More than 100 are in various stages of development[9]. They aim to address some of the existing blockbuster drugs' limitations: the need for frequent injection, nasty side effects and their ineffectiveness for some people.

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There have already been two SCAs filed against companies with GLP-1 drugs.

Semaglutide was first approved by the European Medicines Agency in 2018 to help those suffering with type 2 diabetes[10]. It's what's known as a GLP-1 receptor agonist, and one of its associated effects is that it slows the rate at which the stomach empties, which is why those who take it feel less hungry.

The history of GLP-1 receptor agonists has been mixed since AstraZeneca secured the first approval in 2005 with their drug Byetta. Several drugs entered the market, only to exit later. It's only Ozempic/Wegovy that has had blockbuster success.

Based on our analysis of the class actions brought against drugmakers who developed unsuccessful cancer and Covid-19 candidates, we expect more class actions to be filed against public drugmakers developing their own GLP-1 agonists.

The race to find a competitor to Ozempic/Wegovy has already resulted in lawsuits. There have been two claims brought against companies so far, one in 2024 and one already in 2025. The allegations against Altimmune, Inc specifically mention how it "overstated the potential for pemvidutide to stand out from competing GLP-1 agonists based on the drug's efficacy and tolerability results observed in the MOMENTUM Trial"[11].

Over the past 5 years, there has evidently been a correlation between blockbuster drugs and SCA frequency against competitors to these drugs in the life science space. As of February 2025, there were 39 new GLP-1 drugs in development from 34 companies[12]. Based on the impact of blockbuster drugs in the cancer and covid-19 space, these companies may give up on the race to compete, or may even turn to combination therapies to demonstrate efficacy and are bound to be hit by preying plaintiffs in the process.

Either way, the D&O team at Inigo are expecting the high frequency of claims against pharmaceutical companies to continue well into 2025 and beyond. We aim to support our client's through this exposure and offer specialist coverage through our Inigo Biotech Protect product.

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Appendix

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