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COMPLAINT CHARGING MODERNA, INC. WITH MISLEADING INVESTORS

I. SUMMARY

Oxfam American is concerned that Moderna, Inc. [hereinafter "Moderna" or "the company"] has filed misleading statements to the SEC. In particular, it appears that Moderna has concealed material risks that have harmed, and that may continue to damage, the company's financial health. These misleading statements and omitted risks appear in the company's 10-K of February 26, 2021[1] and the 10-Q of November 4, 2021,[2] and include 1) framing actual risks that have already occurred as hypothetical risks; and 2) failing to acknowledge the risk of litigation contemplated by the U.S. government.

Specifically, Moderna cast patent disputes as a risk that "may" occur, when in reality the U.S. government and Moderna have been embroiled in such conflict for over one year. The two are locked in a dispute over invention rights to the mRNA 1273 vaccine that US government and Moderna scientists developed in close collaboration. This patent dispute has been dissected at length in mainstream media outlets like the New York Times,[3] Forbes,[4] and the Wall Street Journal.[5] Despite the ongoing nature of the dispute, Moderna's SEC filings framed this disagreement over patent rights as purely theoretical in nature. Nor did the company acknowledge in its SEC filings that the U.S. government could be the likely opponent when discussing hypothetical patent disputes, instead publishing generic risk disclosure like "[o]ther companies or

[1] Moderna, Inc., 10-K, (Feb. 26, 2021), https://investors.modernatx.com/static-files/6c67452f-6a27-47a2-8ee7-48d18c54ea4c.
[2] Moderna, Inc., 10-Q, (Nov. 4, 2021), https://investors.modernatx.com/static-files/3453d9e3-0ee6-4391-a567-add2b5493df2.
[3] Sheryl Gay Stolberg and Rebecca Robbins, Moderna and U.S. Government at Odds Over Vaccine Patent Rights, NY Times, (Nov. 11, 2021) https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html.
[4] Robert Hart, Government Battle Looms Over Who Should Take Credit for Moderna Vaccine, Forbes, (Nov. 11, 2021) https://www.forbes.com/sites/roberthart/2021/11/11/government-legal-battle-looms-over-who-should-take-credit-for-moderna-vaccine/?sh=1897714824c4.
[5] The Editorial Board, Biden's Moderna Vaccine Double Cross, The Wall Street Journal, (Oct. 4, 2021) https://www.wsj.com/articles/bidens-covid-vaccine-double-cross-moderna-patent-11634248823.

organizations may challenge our patent rights."[6] It is clear that investors find this information material: following public reports that the National Institute of Health (NIH) was threatening litigation should Moderna continue attempts to claim sole inventorship rights, the company's stock fell to a five-month low.[7] Additionally, as will be detailed below, the fact that Moderna relies so heavily upon this disputed product as the exclusive source of its profits, that its vaccine is subject to intense public and governmental scrutiny, and that an average reasonable investor would have found the U.S. government-Moderna dispute a critical element in determining the stock's value all indicate the company failed to disclose a material risk.

Second, Moderna failed to disclose litigation that it knows to be contemplated by the U.S. government, as required by 17 CFR § 229.103(a).[8] Rather than acknowledge the risk of litigation – which the company should have known was a "more than remote" possibility – Moderna's most recent 10-Q simply states, "[f]rom time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently a party to any material legal proceedings."[9] This statement conceals that the NIH is openly contemplating litigation because of the company's refusal to share inventorship credit. While the February 10-K discusses the prospect of patent litigation in more detail, it relies upon generic language and does not specify that litigation was contemplated by the *U.S. government*, a critical omission that violates the express provisions of the SEC's updated SK-103 legal risks disclosure requirements. The company's more recent statement that it would "pause" the filing of the patent pending further conversation with the government suggests that the company has been "feeling the heat;" while investors welcome such a pause, it simply "kicks the can down the road" rather than makes the threat of litigation disappear.[10]

We believe that these deceptive and ambiguous statements were designed to hide damaging information from investors. This violates Sections 10(b) and 20(a) of the Exchange Act, which require publicly traded companies to file SEC reports with accurate information that does not mislead investors.

II. Risk Disclosure Failure: Misleading Investors on Ongoing Patent Dispute with U.S. Government

This complaint will provide a brief overview of the patent dispute between the U.S. government and Moderna, and then will examine how the company's 2021 SEC filings present the dispute exclusively in hypothetical terms. Next, it will review relevant SEC regulations and recent enforcement actions and assess how these standards measure up against Moderna's filings.

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[6] Moderna, Inc., 10-K, 131, (Feb. 26, 2021), https://investors.modernatx.com/static-files/6c67452f-6a27-47a2-8ee7-48d18c54ea4c. Given that the November 10-Q states, "There have been no material changes from the risk factors previously disclosed in the Annual Report on Form 10-K," any risk listed in the 10-K should be read as Moderna's disclosure of risks as of November 2021.

[7] On November 13, 2021, two days after public revelations of the ongoing patent dispute between Moderna and the U.S. government, Moderna's stock price sunk to its lowest level since June 2021 - $225.82. (Note the stock had already started to dip as a result of disappointing Q3 report that showed Moderna had underdelivered on its promised vaccines by a significant volume). The fact that the stock fell to a five-month low as news of the patent dispute was revealed illustrates that investors place high value on this information and may choose to value the stock less with this dispute in mind. The history of Moderna's stock price may be found here: CNBC, Moderna, Inc., https://www.cnbc.com/quotes/MRNA (last accessed Dec. 11, 2021).

[8] 17 CFR § 229.103(a) (emphasis added), *available at* https://www.ecfr.gov/current/title-17/chapter-II/part-229/subpart-229.100/section-229.103.

[9] Moderna, Inc., 10-Q, (Nov. 4, 2021), https://investors.modernatx.com/static-files/3453d9e3-0ee6-4391-a567-add2b5493df2.

[10] Dan Diamond, Moderna Halts Patent Fight over Coronavirus Vaccine with Federal Government, The Washington Post (Dec. 17, 2021) https://www.washingtonpost.com/health/2021/12/17/moderna-vaccine-patent-dispute-nih/.

A. U.S. Government-Moderna Dispute

The invention at issue – the sequencing of the mRNA 1273 vaccine – was created following close collaboration between scientists from the NIH, the National Institute of Allergy and Infectious Diseases (NIAID), and Moderna, with significant support from scientists from UNC Chapel Hill, the University of Texas at Austin, and Vanderbilt University Medical Center. Disagreement over ownership rights soon emerged. NIH publicly affirmed its inventorship role in designing the spike protein sequence encoded in mRNA-1273.[11] Moderna claims it developed the sequence independently, issuing the following statement on its website:

> We do not agree that NIAID scientists co-invented claims to the mRNA (modified nucleotide) sequence of our COVID-19 vaccine. The mRNA sequence was selected exclusively by Moderna scientists using Moderna's technology and without input of NIAID scientists, who were not even aware of the mRNA sequence until after the patent application had already been filed. Therefore, only our scientists can be listed as the inventors on these claims.[12]

While Moderna posted this statement in November 2021, evidence suggests this dispute had long been brewing. According to a National Institutes of Health letter sent in November 2021, "NIH asserted in discussions with Moderna *more than a year ago* that three NIH scientists were co-inventors of the mRNA-1273 patent claims, not just methods of use, and should be named as such."[13]

Testimony from Dr. David Kessler, Chief Science Office of the government's COVID-19 response, similarly indicates that the U.S. government and Moderna's dispute have been underway for quite some time. During a recent congressional hearing with the House Appropriations Committee, Dr. Kessler discussed the inventorship conflict at some length, the fact that it had been brought to the attention of the company's senior leadership including the Board of Directors and Senior Management, and responded to a question on inventorship with the remark "**I will let the lawyers at NIH and the Department of Justice who are handling this respond. I am not part of those negotiations**."[14] The presence of DOJ attorneys in negotiations suggests the dispute had been longstanding and tense.

Indeed, Moderna's own patent applications clearly indicate that the company was aware of a dispute: their July 2021 patent filing acknowledges that "collaborators at the National Institutes of Health submitted John Mascola, M.D.; Barney Graham, M.D., Ph.D; and Kizzmekia Corbett, Ph.D. to Applicants as additional co-inventors of this patent application. However, Applicants have reached the good-faith determination that these individuals did not co-invent the mRNAs and mRNA compositions claimed in the present application."[15]

This conclusion is further supported by the press. Media reports of a longstanding patent dispute similarly indicate that Moderna was aware that such disagreement was already occurring at times when the company

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[11] Public Citizen, Letter Urging NIH to Reclaim Role in Moderna Vaccine, (Nov. 2, 2021) https://www.citizen.org/article/letter-urging-nih-to-reclaim-foundational-role-in-nih-moderna-vaccine/.

[12] Moderna, Statement on Intellectual Property, (Nov. 11, 2021), https://investors.modernatx.com/news-releases/news-release-details/statement-intellectual-property

[13] Public Citizen, NIH response to Public Citizen, (Dec. 3, 2021), https://www.citizen.org/article/nih-responds-to-public-citizen-moderna-patent-letter/.

[14] Testimony of Dr. David Kessler before the House Committee on Appropriations, U.S. Role in Global COVID-19 Vaccine Equity, (Nov. 19, 2021, 1:15:32), https://appropriations.house.gov/events/hearings/us-role-in-global-covid-19-vaccine-equity (emphasis added).

[15] United States Patent and Trademark Office, Coronavirus RNA Vaccine Patent Application, Docket No. M1378.70145US0, July 28, 2021, https://int.nyt.com/data/documenttools/moderna-patent-filing/7b73f4609cf965c8/full.pdf.

presented such disputes as hypothetical (discussed in part B below). On November 11, 2021, the New York Times reported that the "N.I.H. had been in talks with Moderna *for more than a year* to try to resolve the dispute."[16] Forbes echoed this timeline, writing that the two had been embroiled in a "*year-long spat* over who invented key parts of Moderna's COVID-19 vaccine, and that "NIH director Dr. Francis Collins [said that] U.S. funded scientists played a role in developing Moderna's Covid-19 vaccine and deserve to be recognized for their work, [and] that the agency is prepared to defend its claim if needed."[17]

Based on this reporting, it is clear that Moderna was aware that a patent dispute was occurring no later than November 2020 – well in advance of its publication of its 10-K in February 2021, and its 10-Q in November 2021, both of which present the patent dispute risk as theoretical (discussed below). Indeed, even if Moderna were somehow ignorant of the NIH's disagreement prior to the November revelations in the NY Times and Forbes – something which strains credulity – the Wall Street Journal also reported on these disagreements in October 2021,[18] in advance of Moderna's most recent 10-Q. The company must have been aware of this patent dispute with the US government and still chose not to disclose it in SEC filings.

The market's reaction to these revelations of a long-simmering clash between Moderna and the NIH confirms that investors had been left in the dark, and that they considered this information material to the valuation of Moderna: Moderna's stock price dropped on the day the New York Times and Forbes published stories about the dispute, and fell to a five-month low two days after those publications.[19]

Moderna's recent behavior demonstrates it is likely aware that this patent dispute is taking a reputational toll and could lead to a costly lawsuit. Last week, the company agreed to temporarily "pause" its patent dispute with the U.S. government by delaying submission of its patent application.[20] This supports the conclusion that Moderna understands that stock price could fall should the patent dispute proceed to court – a known risk that was not explicitly acknowledged in its SEC filings. Furthermore, it is worth noting that the announcement merely suspends, but does resolve, the dispute; Moderna has reserved the right to file a patent application that excludes NIH scientists from inventorship rights. Because the company declines to state it will rule out resuming this patent dispute, it is effectively "kicking the can down the road" – and effectively ensuring the risk for investors remains.[21]

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[16] Sheryl Gay Stolberg and Rebecca Robbins, Moderna and U.S. Government at Odds Over Vaccine Patent Rights, NY Times, (Nov. 11, 2021) https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html (emphasis added).

[17] Robert Hart, Government Battle Looms Over Who Should Take Credit for Moderna Vaccine, Forbes, (Nov. 11, 2021) https://www.forbes.com/sites/roberthart/2021/11/11/government-legal-battle-looms-over-who-should-take-credit-for-moderna-vaccine/?sh=1897714824c4.

[18] The Editorial Board, Biden's Moderna Vaccine Double Cross, The Wall Street Journal, (Oct. 4, 2021) https://www.wsj.com/articles/bidens-covid-vaccine-double-cross-moderna-patent-11634248823.

[19] On November 13, 2021, Moderna's stock price sunk to its lowest level since June 2021 - $225.82. (Note the stock had already started to dip as a result of disappointing Q3 report that showed Moderna had underdelivered on its promised vaccines by a significant volume). The history of Moderna's stock price may be found here: CNBC, Moderna, Inc., https://www.cnbc.com/quotes/MRNA (last accessed Dec. 11, 2021).

[20] Robert Langreth and Susan Decker, Moderna Delays Patent Application on COVID Shot Patent Disputed by NIH, Bloomberg, (Dec. 17, 2021), https://www.bloomberg.com/news/articles/2021-12-17/moderna-delays-patent-application-on-covid-shot-for-nih-talks#:~:text=Moderna%20Inc.%20said%20it%20has,allowing%20more%20time%20for%20negotiations.

[21] Dan Diamond, Moderna Halts Coronavirus Dispute with NIH over Coronavirus Vaccine, The Washington Post, (Dec. 17, 2021), https://www.washingtonpost.com/health/2021/12/17/moderna-vaccine-patent-dispute-nih/.

B. Moderna's SEC Filings

Despite the well-documented disagreement, Moderna's SEC filings present the risk of patent dispute in hypothetical terms.

Moderna's most recent 10-Q filing, submitted on November 4, 2021, discusses risk in general language. For example, the company writes about potential risks such as "government actions and restrictive measures implemented in response [to COVID-19]"[22] and "the scope of protection we are able to establish and maintain for intellectual property rights."[23] However, neither of these risks are fleshed out with specificity, nor do they disclose the longstanding IP dispute. The risk of IP disagreement is presented as speculative.

Moderna's 10-Q then directs investors and other stakeholders to review its February 10-K for a more comprehensive overview of risk factors, and writes that as of November 2021, there "***have been no material changes from the risk factors previously disclosed in the Annual Report on Form 10-K.***"[24] The company's 10-K, in turn, certainly flags patent disputes, but reports them as merely hypothetical concerns. For example:

- In the Summary of Material Risks section, Moderna acknowledges that "[o]ther companies or organizations ***may*** challenge our patent rights;"[25]
- It later explains, "We ***may*** be subject to claims challenging the inventorship or ownership of our patents and other IP. We ***may*** be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other IP. Ownership disputes ***may*** arise, for example, from conflicting obligations of consultants or others who are involved in developing our development candidates."[26]

As such, Moderna presents the risk of patent disputes in theoretical terms. However, as discussed in part A above, the company had already been mired conflict with NIH for approximately one year as of November 2021, meaning that both the company's 10-K and 10-Q were misleading.

It appears Moderna used ambiguous language like "claims," "challenge," and "dispute"[27] so that the company could plausibly argue that those terms should be interpreted as "litigation" – in which case the company might argue that it was flagging potential *litigation* here, which has not yet occurred, and was not flagging other types of conflicts. However, given that Moderna specifies "litigation" elsewhere when its filings mean precisely that, "dispute" and "challenge" therefore have broader meanings that would encompass other types of disagreements that do not rise to the level of "litigation." Investors' adverse reaction to the revelation of this news about the patent dispute with NIH suggests that investors were previously unaware of the depth and intensity of the patent dispute – which Moderna glossed over in its SEC filings. In sum, the company's use of "may" when it should have presented those disputes as currently occurring likely misled investors.

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[22] Moderna, Inc., 10-Q, p. 2, (Nov. 4, 2021), https://investors.modernatx.com/static-files/3453d9e3-0ee6-4391-a567-add2b5493df2.

[23] *Id.*

[24] *Id.* at p. 50.

[25] Moderna, Inc., 10-K, p. 3, (Feb. 26, 2021), https://investors.modernatx.com/static-files/6c67452f-6a27-47a2-8ee7-48d18c54ea4c (emphasis added).

[26] Moderna, Inc., 10-K, p. 136, (Feb. 26, 2021), https://investors.modernatx.com/static-files/6c67452f-6a27-47a2-8ee7-48d18c54ea4c.

[27] *Id.* at 126 (avoiding the word "litigation" with phrasing like, "We cannot be certain that such patent will survive or that the claims will remain in the current form. In addition, third parties may attempt to invalidate our IP rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our IP rights.")

C. Relevant Standards

Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. § 78(a)] provide that any issuer of securities provide the SEC with accurate information that does not mislead investors. Misleading statements may be about "financial performance, risk factors, and failing to disclose known industry trends."[28] Under Regulation S-K Item 303, for example, public companies must "[d]escribe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations."[29] As logic dictates and SEC Enforcement Actions confirm, protracted disagreement with governmental authorities can constitute both a risk and an uncertainty that must be disclosed.

When weighing whether misleading statements constitute securities fraud, key considerations include 1) whether the risk was material to investors; 1a) the degree of public and governmental scrutiny around the product in question; 1b) the centrality of the product in the company's financial health; and 2) whether an actual risk that has already occurred is presented as hypothetical. Each will be considered in turn.

1. Materiality

Risk disclosure centers on evaluations of whether an omitted risk was "material." The SEC recently lowered the disclosure requirement from listing "most significant" to "material" risks.[30] This expands the number of actual and potential risks that a company must disclose.

The definition of "material risk" is ambiguous and subject to significant debate. The SEC has defined this as "the information required to those matters as to which an average prudent investor ought reasonably to be informed before buying or selling any security of the particular company."[31] An SEC Staff Accounting Bulletin clarifies that this calculation contains both qualitative and quantitative factors to consider. From a quantitative perspective, auditors use five to ten percent of net income as a general guide.[32] Quantitative factors include considerations like whether the misstatement concerns a product that constitutes a large percentage of the entity's profitability, whether it masks a change in trends or earnings, or whether it hides a failure to meet analysts' expectations.[33]

The Supreme Court has provided similar guidance, noting that what "the standard does contemplate is a showing of a substantial likelihood that, under all the circumstances, the omitted fact would have assumed actual significance in the deliberations of the reasonable shareholder. Put another way, there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available."[34] In brief, material facts are those that have a bearing on an investment or voting decision.

A patent dispute between the NIH and Moderna easily meets this materiality standard. An average investor would want to know whether there is conflict between Moderna and the U.S. government over ownership

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[28] *Selected Division of Enforcement Accomplishments: December 2016–December 2020*, SEC (Dec. 30, 2020), https://www.sec.gov/enforce/selected-division-enforcement-accomplishments-december-2016-december-2020.
[29] *See Ind. Pub. Ret. Sys. v. SAIC, Inc*., 818 F.3d 85, 94 (2d Cir. 2016) (citing 17 C.F.R. § 229.303(a)(3)(ii)).
[30] SEC, 17 CFR 229, 239, and 240, Modernization of Regulation SK Items 101, 103, and 105, https://www.sec.gov/rules/final/2020/33-10825.pdf.
[31] 17 CFR Sec. 270.8(b)(2) (emphasis added).
[32] Thomas A. Sporkin and Meredith Leeson, SEC Risk Factors: A Single Wrong Word Could Cost Millions, American Bar Association, (Jan. 17, 2020) https://www.americanbar.org/groups/business_law/publications/blt/2020/02/sec-risk-factors/.
[33] SEC Staff Accounting Bulletin, No. 99: Materiality, https://www.sec.gov/interps/account/sab99.htm.
[34] *TSC Industries v. Northway, Inc*., 426 U.S. 438, 449 (1976).

rights, as this has significant financial implications for the company. Indeed, the market registered a notable drop in stock price following the public revelation of the dispute.

1.a. Public and governmental scrutiny

Public and governmental scrutiny over a product indicates that statements about said product are material to investors. In the enforcement action brought against Mylan, for example, the SEC honed in on the fact that the company became the subject of significant public and political attention time during the period in question.[35] In addition, the SEC complaint noted that governmental scrutiny coincided with a drop in stock price: "On September 2, 2016, Mylan's stock price dropped significantly (4.7%) after news outlets widely reported that members of Congress accused Mylan of misclassifying EpiPen and underpaying the government."[36]

It is an understatement to say that the mRNA 1273 vaccine as a whole, and the ownership rights in particular, are the subject of intense public and governmental scrutiny. The vaccine and the dispute have been widely examined in the press, and there are significant implications for the public at large depending upon which entity(-ies) eventually establish ownership rights. Intense public scrutiny is also apparent from the dip in stock price following the publication of articles which chronicled the patent dispute.

1.b. Centrality of Product in the Company's Financial Health

In addition, a company's assertion is more likely to be material when the product in question generates a significant percentage of that company's profits. Misleading investors about a core part of a company's business threatens to harm investors in far greater ways than omissions about relatively insignificant products or services. In the SEC's enforcement action against Mylan, the fact that EpiPen constituted such a large percentage of the pharmaceutical company's income "could have significant and potentially material financial consequences."[37]

The financial success of the mRNA 1273 COVID vaccine is core to Moderna's business. In fact, the vaccine is the company's only product: "Unlike Pfizer, Johnson & Johnson and AstraZeneca, which have a diverse roster of drugs and other products, Moderna sells only the COVID vaccine. The Massachusetts company's future hinges on the commercial success of its vaccine."[38] Misleading investors about risks that can damage the financial success of a company's *single commercially successful product* – such as a heated dispute over the mRNA 1237 vaccine – renders the misleading statements highly material.

2. "May" versus "Has"

The SEC also surveils whether companies are honest about whether risks *may* occur versus whether they *have already* occurred. Statements that frame risks as hypothetical when they have materialized violate securities law. Three recent enforcement actions bear this out:

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[35] Columbia Law School Sky Blog, Cleary Gottlieb Discusses SEC Action for Non-Disclosure of DOJ Investigation, https://clsbluesky.law.columbia.edu/2019/10/15/cleary-gottlieb-discusses-sec-action-for-non-disclosure-of-doj-investigation/#_ftn3.

[36] *SEC v. Mylan*, Complaint, Case No. 1:19-CV-2904,
D.C. Cir., (Sept. 27, 2019), at 2, *available at* https://www.sec.gov/litigation/complaints/2019/comp-pr2019-194.pdf.

[37] *Id.*

[38] Rebecca Robbins, Moderna, Racing for Profits, Keeps Vaccine Out of Reach of Poor, (Oct. 9, 2021), https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html.

- The SEC fined Facebook for a filing that stated "our users' data may be improperly accessed," when the company was *already aware* that a user data breach had occurred;[39]
    - As the SEC complaint relates, "Facebook's Risk Factor disclosures misleadingly suggested that the company faced merely the risk of such misuse and any harm to its business that might flow from such an incident. This *hypothetical phrasing, repeated in each of its periodic filings during the relevant period,* created the false impression that Facebook had not suffered a significant episode of misuse of user data by a developer."[40]
- The SEC pursued action against Mylan in part because its risk disclosure stated that the Center for Medicaid and Medicare Services (CMS) "may" take a position adverse it, whereas CMS had already informed Mylan that it disagreed with its EpiPen classification;[41] and
- The SEC fined Pearson Plc $1 million for presenting a data breach that had already occurred as a hypothetical risk.[42]

As such, companies should not frame actual risks as potential – particularly, as the Mylan case illustrates, when that actual risk involves disagreement with government officials.

As discussed above, Moderna's SEC filings frame all patent disagreements as disputes that "may" occur, rather than acknowledging that they "have" occurred for at least one year. Neither the February 10-K nor the November 10-Q acknowledge any ongoing discussions between Moderna and attorneys at DOJ and NIH, tensions between the two, or probable litigation with the NIH over ownership rights. While it would be acceptable for Moderna to discuss *litigation* as a hypothetical risk,[43] given the intensity of the dispute and the adverse impact it had on stock price when the risk spilled out into the open, it is inaccurate to frame the risk of any *dispute* or *claim* to ownership rights as hypothetical. Patent disputes are not a risk – they are a reality.

D. Summary of Misleading Investors on Risk

In sum, Moderna misled investors about the risks related to a patent dispute with the U.S. government. This poses a material risk to investors, given the weight that an average prudent would accord such a conflict, the significant public and governmental scrutiny on the COVID-19 vaccine in dispute, and the critical role that the vaccine plays in the company's financial health. Furthermore, the company's suggestion that such inventorship conflicts "may" occur, as opposed to disclosing that these conflicts have been long brewing, indicate that the company intentionally misled investors. That the company's stock fell to a five-month low following these public revelations only serves to underscore that Moderna employed this deceptive language to avoid a financial loss.

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[39] Thomas A. Sporkin and Meredith Leeson, SEC Risk Factors: A Single Wrong Word Could Cost Millions, American Bar Association, (Jan. 17, 2020) https://www.americanbar.org/groups/business_law/publications/blt/2020/02/sec-risk-factors/.

[40] *SEC v Facebook*, Complaint, Case No. 3:19-cv-04241, N.D. Cal, ¶ 39, https://www.sec.gov/litigation/complaints/2019/comp-pr2019-140.pdf (emphasis added).

[41] Columbia Law School Sky Blog, Cleary Gottlieb Discusses SEC Action for Non-Disclosure of DOJ Investigation, https://clsbluesky.law.columbia.edu/2019/10/15/cleary-gottlieb-discusses-sec-action-for-non-disclosure-of-doj-investigation/#_ftn3.

[42] SEC, "SEC Charges Pearson Plc with Misleading Investors about Cyber Breach," (Aug. 16, 2021) https://www.sec.gov/news/press-release/2021-154

[43] Moderna's filings clearly distinguish between litigation risks, which it clearly calls out as litigation risk when appropriate, and more amorphous terms such as "disputes," "claims," and "challenges." Moderna should not be permitted to assert that when it uses the word "claim" or "dispute" or "challenge," that can only mean "litigation" – the logical extension of that potential argument being "we said patent disputes are hypothetical because there are no lawsuits already filed in court." Investors agree that it is appropriate for Moderna to disclose patent litigation risk as hypothetical; patent conflict (or disputes, claims, or challenges), by contrast, have already been taking place for months.

III. LEGAL RISK DISCLOSURE FAILURE: MISLEADING INVESTORS ON PROSPECTS FOR LITIGATION WITH THE U.S. GOVERNMENT

The complaint will review the possible litigation between NIH and Moderna, and detail how Moderna has framed legal risk its SEC filings. Next, the complaint will examine relevant SEC regulations and recent enforcement actions related to legal risk disclosure and describe how Moderna's statements fall short.

A. Threats of Litigation

Recent news reports document the increasing prospect of litigation between the NIH and Moderna. On November 10, 2021, the NY Times wrote that "The National Institutes of Health is prepared to aggressively defend its assertion that its scientists helped invent a crucial component of the Moderna coronavirus vaccine — including taking legal action if government lawyers deem it necessary, the agency's director said on Wednesday."[44] The next day, the paper continued on to explain that "The N.I.H. had been in talks with Moderna for more than a year to try to resolve the dispute; the company's July filing caught the agency by surprise…If the two sides do not come to terms by the time a patent is issued, the government will have to decide whether to go to court — a battle that could be costly and messy."[45] Forbes catalogued the NIH's displeasure with Moderna the same day, writing, "NIH director Dr. Francis Collins told Reuters Wednesday U.S. funded scientists played a role in developing Moderna's Covid-19 vaccine and deserve to be recognized for their work, adding that the agency is prepared to defend its claim if needed. Collins indicated that the matter could be headed to court, telling Reuters it is clear the dispute is something "legal authorities are going to have to figure out" as both parties have been unable to resolve the conflict amicably."[46]

More telling still was the testimony of Dr. David Kessler. As discussed above, during his testimony before the House Appropriations Committee, Dr. Kessler revealed that **attorneys from the Department of Justice and NIH have been and continue to be involved in the NIH-Moderna dispute**.[47] In a response to a question regarding co-ownership and licensing, Dr. Kessler commented, "I will let the lawyers at NIH and the Department of Justice who are handling this respond. I am not part of those discussions." Congressman Ben Cline persists, asking, "But it's safe to say they are ongoing?" Dr. Kessler concludes, "I will defer again to counsel who are negotiating these issues."[48] Furthermore, his testimony makes clear that this dispute was brought before the company's highest authorities; after detailing the government's position on co-ownership and lamenting that "Moderna has so far refused to name the government scientists to the

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[44]Sheryl Gay Stolberg and Rebecca Robbins, The NIH Isn't Giving Up in Its Patent Fight with Moderna, The NY Times, (Nov. 10, 2021) https://www.nytimes.com/2021/11/10/us/politics/moderna-vaccine-patent-nih.html.

[45] Sheryl Gay Stolberg and Rebecca Robbins, Moderna and U.S. Government at Odds Over Vaccine Patent Rights, The NY Times, (Nov. 11, 2021) https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html (emphasis added).

[46] Robert Hart, Government Battle Looms Over Who Should Take Credit for Moderna Vaccine, Forbes, (Nov. 11, 2021) https://www.forbes.com/sites/roberthart/2021/11/11/government-legal-battle-looms-over-who-should-take-credit-for-moderna-vaccine/?sh=1897714824c4.

[47] Testimony of Dr. David Kessler before the House Committee on Appropriations, U.S. Role in Global COVID-19 Vaccine Equity, (Nov. 19, 2021, beginning at 1:15:32), https://appropriations.house.gov/events/hearings/us-role-in-global-covid-19-vaccine-equity (emphasis added).; *see also* Tweet from Zain Rizvi,(Nov. 17, 2021, 1:17pm) https://twitter.com/zainrizvi/status/1461035732886331399.

[48] Testimony of Dr. David Kessler before the House Committee on Appropriations, U.S. Role in Global COVID-19 Vaccine Equity, (Nov. 19, 2021, beginning at 1:15:32), https://appropriations.house.gov/events/hearings/us-role-in-global-covid-19-vaccine-equity (emphasis added).

principle patent application," Dr. Kessler commented that "We have gone to the extent of calling in and discussing this with the Chair of the Board of Moderna, members of the board, as well as the Senior Management of Moderna."[49] A dispute with DOJ, particularly one brought to the attention of the company's most senior management and the full board directors, presents a clear risk, as detailed below, and must be disclosed to investors.

While these articles were published after Moderna's most recent 10-Q, given the protracted dispute, NIH Director Collin's firm assertions over the summer of 2021 that the NIH had ownership rights in the mRNA 1273 vaccine and would fight to protect them,[50] and DOJ attorneys' involvement in the dispute, Moderna knew or should have known that the government would consider litigating prior to the filing of its 10-Q.

Finally, as mentioned above, the company's recent announcement that it will temporarily "pause" the patent application[51] (and, for the time being, avoid the litigation that could possibly ensure) only serves to underscore Moderna's understanding that a legal battle would be very costly to the company and its investors – a risk the company chose not to clearly disclose.

B. Standards on Legal Risk Disclosure

In 2020, the SEC updated the disclosure requirements surrounding legal risk. CFR § 229.103(a) requires companies to:

> Describe briefly any material pending legal proceedings, other than ordinary routine litigation incidental to the business, to which the registrant or any of its subsidiaries is a party or of which any of their property is the subject….**Include similar information as to any such proceedings known to be contemplated by governmental authorities."**[52]

The inclusion of the phrase "by governmental authorities" signals that the SEC, and in turn investors, are particularly concerned with the prospect of litigation by the *government*, above and beyond corporate competitors or employees. And this makes sense: the reputational stain of being sued by regulators or government agencies is significant, as it casts doubt on the company's legal and ethical compass in ways that routine litigation between companies does not.

While the precise contours of the law remain unclear, given its recent adoption, the surrounding context is instructive: the SEC updated SK-103 in the aftermath of the Mylan enforcement action, in which it disagreed with Mylan that the company had no responsibility to disclose because government litigation was uncertain. The SEC explained that the company should have disclosed the prospect for litigation when material loss became a "reasonably possible (i.e., when the chance of the future event became more than remote, but less than likely)."[53] Notably, the SEC found the participation of DOJ attorneys in the dispute between Mylan and other governmental authorities highly probative of the fact that the company should have known litigation was a reasonable possibility.

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[49] *Id.* at 38:20-39:00.
[50] National Institute of Health Statement to Axios, https://www.documentcloud.org/documents/6956323-NIH-Statement-to-Axios.html.
[51] Dan Diamond, Moderna Halts Coronavirus Dispute with NIH over Coronavirus Vaccine, The Washington Post, (Dec. 17, 2021), https://www.washingtonpost.com/health/2021/12/17/moderna-vaccine-patent-dispute-nih/.
[52] 17 CFR § 229.103(a), *available at* https://www.ecfr.gov/current/title-17/chapter-II/part-229/subpart-229.100/section-229.103.
[53]Columbia Law School Sky Blog, Cleary Gottlieb Discusses SEC Action for Non-Disclosure of DOJ Investigation, https://clsbluesky.law.columbia.edu/2019/10/15/cleary-gottlieb-discusses-sec-action-for-non-disclosure-of-doj-investigation/#_ftn3.

Finally, a materiality standard is built directly into the regulation: CFR § 229.103(b)(2) restricts the legal risk disclosure requirement only to litigation in which damages involved would constitute 10% or more of the company's current assets.[54]

C. Moderna's SEC Filings

Moderna's November 10-Q acknowledges legal risk in generic terms that offer investors no meaningful information: "[f]rom time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently a party to any material legal proceedings."[55] That is the totality of the legal risk Moderna's November filing recognized.

The 10-Q also references the company's 10-K as providing an exhaustive list of material risks – including litigation. This February 2021 document provides more detail for investors. When discussing patent disputes, for example, the company writes, "[o]wnership disputes may arise…. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership."[56] It also states that "[t]here is uncertainty about which patents will issue, and, if they do, as to when, to whom, and with what claims. It is likely that there will be significant litigation and other proceedings."[57]

While the complainant appreciates that Moderna recognized litigation as a possibility, this disclosure remains insufficient. The company carefully avoided noting that litigation was contemplated by governmental authorities – a key distinction – and often opted for vague terms that may or may not encapsulate litigation. Rather than acknowledge that the government may sue the company for attempting to monopolize the ownership rights – something that the company knew was in the offing given the yearlong dispute – Moderna instead skirted around SK-103's requirements, imagining the potential litigant as "former employees, collaborators, or other third parties."[58] Moderna's failure to specifically acknowledge possible legal action by the government violates SK-103. While "collaborators" do include governmental authorities, and "other third parties" appears to be an attempt at crafting a catchall, an investor unfamiliar with the NIH-Moderna patent dispute may not understand this as meaning there is potential litigation from a governmental agency. This ambiguity paints a misleading picture to investors of the actual legal risk faced by Moderna. Moderna repeatedly mentions governmental authorities in other parts of the 10-K, suggesting it understands the distinction between "government" actors and the more generic "parties," and chose the latter to gloss over potential litigation with the US government.

Along similar lines, the SEC filings select the words "litigation," "claim," "dispute," and "challenge" strategically. The company attempts to use the umbrella terms like "claim," "dispute," and "challenge" when it discusses confrontations with the U.S. government. Any time "litigation" is explicitly mentioned, however, the company switches to unspecific actors like "third parties." Indeed, it appears that Moderna goes to great pains to avoid combining the words "government" and "litigation" in the same sentence. This attempt to prevent investors from clearly understanding that litigation is contemplated by the U.S. government, which Moderna is very much aware of, constitutes a direct violation of SK-103.

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[54] 17 CFR § 229.103(b)(2), *available at* https://www.ecfr.gov/current/title-17/chapter-II/part-229/subpart-229.100/section-229.103.
[55] Moderna, Inc., 10-Q, p. 49, (Nov. 4, 2021), https://investors.modernatx.com/static-files/3453d9e3-0ee6-4391-a567-add2b5493df2.
[56] Moderna, Inc., 10-K, p. 136, (Feb. 26, 2021), https://investors.modernatx.com/static-files/6c67452f-6a27-47a2-8ee7-48d18c54ea4c.
[57] *Id.* at 131.
[58] *Id.* at 136.

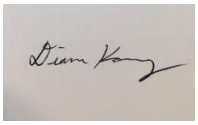
Finally, it bears mention that the "more than remote, but less than likely" standard[59] for disclosing risk of governmental litigation is easily met. Moderna was in heated talks with NIH for over one year when they published the most recent 10-Q that omits any mention of risk of governmental litigation. Yet companies must disclose information about any proceedings known to be contemplated by governmental authorities (SK-103), as soon as there is a "reasonable possibility" – when the chance becomes more than remote, but less than likely. Moderna must have known that the chance of litigation was not implausible, as the company's dispute with the NIH has dragged on for more than one year and the DOJ intervened. While there is little precedent articulating just what "known to be contemplated" requires, logic dictates that repeated and seemingly intractable disputes, DOJ attorneys becoming involved in the conflict, coupled with administration officials leaking stories of intense displeasure and the NIH Director's on-the-record statements about the agency's intent to protect its patent rights in court, indicate Moderna was surely aware that risk of a lawsuit was "more than remote."

VI. Conclusion

Moderna's most recent 10-K and 10-Q filings misled investors regarding the ongoing patent dispute with the NIH and the "more than remote" likelihood that the U.S. government would initiate legal proceedings. This violates Section 10(b) and 20(a) of the Exchange Act [15 U.S.C. § 78(a)]. In addition, a litany of factors considered in the SEC Enforcement Manual suggest that this breach stands as one particularly important to address: the size of the potential victim group is large (all Moderna investors), the extent of the potential loss is significant (the reputational damage of patent disputes and litigation is substantial, and even rumors of such harm share value as the November stock decline demonstrates), the opportunity to send a message of deterrence is high (Moderna is currently among the world's most high-profile public companies), and the matter involves misconduct by persons occupying positions of substantial authority and who own enhanced duties and obligations to a broad group of investors or others (few actors have more ability to vaccinate the world and end the pandemic than Moderna).[60] The complainant requests that the SEC open a Matter Under Inquiry or Investigation into Moderna to protect investors from the material risk that such misleading statements regarding the patent dispute pose.

Please feel free to contact me with any questions or comments. Any communication may be directed to Diana Kearney at diana.kearney@oxfam.org.

Respectfully,



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[59] Columbia Law School Sky Blog, Cleary Gottlieb Discusses SEC Action for Non-Disclosure of DOJ Investigation, https://clsbluesky.law.columbia.edu/2019/10/15/cleary-gottlieb-discusses-sec-action-for-non-disclosure-of-doj-investigation/#_ftn3.

[60] *Enforcement Manual*, SECURITIES AND EXCHANGE COMMISSION DIVISION OF ENFORCEMENT 15 (Nov. 28, 2017), https://www.sec.gov/divisions/enforce/enforcementmanual.pdf.