

## Article

# Surveillance of U.S. corporate filings provides a proactive approach to inform tobacco regulatory research strategy

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**Abstract:** The popularity of electronic cigarettes in the United States and around the world has led to a startling rise in youth nicotine use. The Juul e-cigarette was introduced in the U.S. market in 2015 and had captured approximately 13% of the U.S. market by 2017. Unlike many other contemporary electronic cigarette companies, the founders behind the Juul® e-cigarette approached their product launch like a traditional high-tech start-up company, not like a tobacco company. This article presents a case study of Juul's corporate and product development history in the context of US regulatory actions. The objective of this article is to demonstrate the value of government-curated archives as leading indicators which can (a) provide insight into emergent technologies and (b) inform emergent regulatory science research questions. A variety of sources were used to gather data about the Juul e-cigarette and the corporations that surround it. Sources included government agencies, published academic literature, non-profit organizations, corporate and retail websites, and the popular press. Data was disambiguated, authenticated, and categorized prior to being placed on a timeline of events. A timeline of four significant milestones, nineteen corporate filings and events, twelve US regulatory actions, sixty four patent applications, eighty seven trademark applications, twenty three design patents and thirty two utility patents related to Juul Labs and its associates is presented spanning the years 2004 through 2020. This work demonstrates the probative value of findings from patent, trademark, and SEC filing literature in establishing a premise for emergent regulatory science research questions which may not yet be supported by traditional archival research literature. The methods presented here can be used to identify key aspects of emerging technologies before products actually enter the market, this shifting policy formulation and problem identification from a paradigm of being reactive in favor of becoming proactive. Such a proactive approach may permit anticipatory regulatory science research and ultimately shorten the elapsed time between market technology innovation and regulatory response.

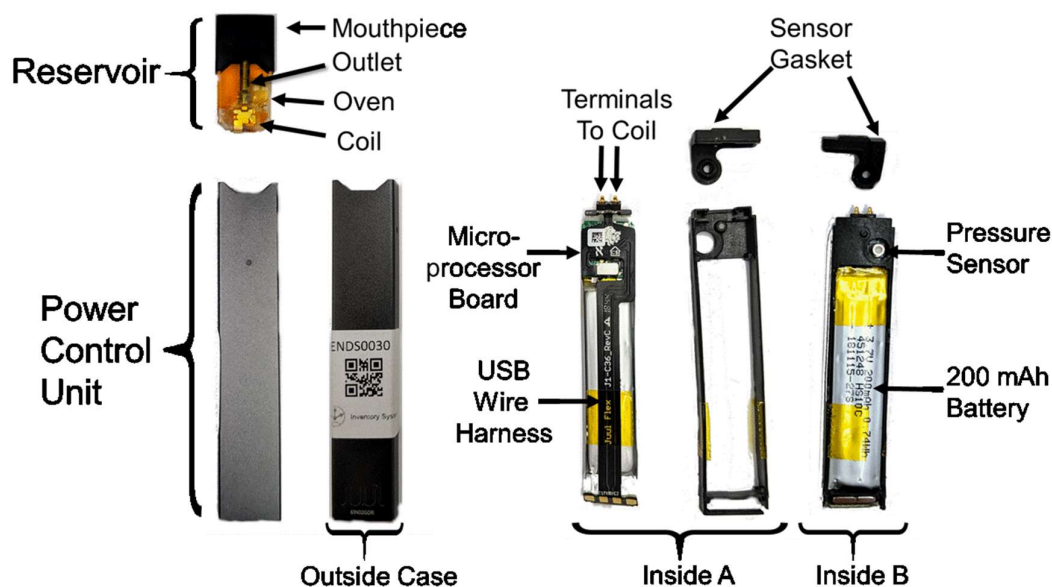
**Keywords:** public health; decision-making; evidence; knowledge; translation; Tobacco Regulatory Science; Tobacco Regulation; e-cigarette; e-cig; vape; Juul

## 1. Introduction

The popularity of electronic cigarettes (e-cigarettes) in the United States has led to a startling rise in youth nicotine use [1,2]. E-cigarette use has acted as a gateway to use of other tobacco or tobacco-related products in non-established cigarette smokers [2]. Since their introduction to the market in 2004, electronic cigarettes have become popular among both cigarette users and nonsmokers. This may be partly because of a misconception that these products are a healthy alternative to cigarettes.

While some studies report e-cigarettes may lead to reduced harm compared to combustible cigarettes [3-8], others contrast with these findings [9-12]. Whether e-cigarettes will yield an overall positive or negative health impact compared to cigarettes remains unknown.

The Juul® e-cigarette (Figure 1) rapidly came to dominate the U.S. market within a year after its 2015 release and led the way in the immense popularity of rectilinear form factor e-cigarettes and nicotine liquid filled pods. The Juul® e-cigarette is composed of two primary subassemblies: the disposable reservoir and power control unit. The non-refillable reservoir contains nominally 0.7 mL of e-liquid composed of a mixture of propylene glycol, glycerin, nicotine and, in some cases, other additives. The top of the reservoir integrates a mouthpiece, which the consumer draws puffs through. The interior of the mouthpiece includes a sophisticated fresh air mixing chamber and flow conditioning pathways. The heating coil is located in the bottom of the reservoir and surrounds a wick to draw e-liquid into contact with the heating coil. The heated oven region of the reservoir is where aerosol is generated by mixing fresh air inlet from the bottom of the reservoir with vaporized e-liquid, and drawn upward through the outlet pipe into the mixing chamber. Two electrical terminals on the bottom surface of the reservoir (not shown) establish the electrical connection to the power control unit. The power control unit consists of an outside case, interior carriage, a microprocessor board, wire harness, 200 mAh lithium battery, and sensor gasket. Sides A and B of the disassembled PCU are illustrated in Figure 1. A four conductor USB wire harness connects the distal user-accessible USB port to the microprocessor board. The presence of four conductors suggests the USB harness has potential both for power and data transfer (+V, ground, data + and data -). The microprocessor board includes battery charging circuitry, puff detection capability, coil voltage control, user feedback via light emitting diode, and data processing capability. The pressure sensor, used for puff detection, is evident on the opposite side B of the microprocessor board. When assembled, the pressure sensor is encased by the sensor gasket to communicate the flow of fresh air. Two terminals connect the positive voltage and ground from the microprocessor board to the coil. Juul Labs™ Inc. has branded the reservoir as a Juulpod™, while many users refer to the disposable reservoirs as “pods.” It is common practice for users, manufacturers and literature to refer to the power control unit simply as the “battery”, obfuscating the potentially sophisticated user feedback and dynamic power control which could dramatically alter aerosol generation and emissions.



**Figure 1.** Annotated photographs of a Juul® electronic cigarette and subcomponents. Photos by Respiratory Technologies Lab, Rochester Institute of Technology.

It has been suggested e-cigarettes may be a harm reduction product for established adult smokers [3-8], but long-term effects of the products and their consumables are not fully established.

E-cigarettes are not harmless; they contain chemicals that may increase risk of cancer and other diseases [13-15]. As of December 2020, the US Food and Drug Administration (FDA) has not approved any e-cigarettes as a cessation therapy. Despite this, several e-cigarette companies, including Juul Labs™ have advertised their product as cigarette replacements. The founders of Juul Labs™ designed their e-cigarette products with the intent of replacing the combustible cigarette [16].

The Juul e-cigarette has been criticized for its contribution to the youth nicotine epidemic in the United States [17-20]. While the relationship between social media and under-aged use of Juul® products have been studied [21-24], there has not been independent, methodological investigation into the history of technology development and the corporate evolution of Juul Labs™. While a common view may be that the Juul e-cigarette rose to a position of market prominence in a fast and surprising manner, the information presented herein documents the decade-long journey from a graduate research project to becoming an “overnight sensation.” In retrospect, many leading indicators were available to see this looming change. This hindsight points to a significant gap in traditional tobacco regulatory research paradigms – emergent regulatory challenges can be anticipated through study of non-traditional research literature.

This article presents a case study of Juul’s corporate and product development history in the context of US regulatory actions. The objective of this article is to demonstrate the value of government-curated archives as leading indicators which can (a) provide insight into emergent technologies and (b) inform emergent regulatory science research questions.

## 2. Methods

### 2.1. Sources of Data

A variety of sources were used to gather data about the Juul e-cigarette and the corporations that surround it. Sources included government agencies, published academic literature, non-profit organizations, corporate and retail websites, and the popular press.

Federal government agencies including the United States (US) Securities and Exchange Commission (SEC), the US Patent and Trademark Office (USPTO), US Center for Disease Control and Prevention (CDC), and the US Food and Drug Administration (FDA) were used to gather publicly available information and were considered authoritative sources. The Electronic Data Gathering, Analysis, and Retrieval (EDGAR) system search tool [25] was used to identify SEC filings related to the corporation. EDGAR is a structured search engine; once a corporate identifier was found that identifier was used to ensure SEC filings relevant to that corporation could be located. Trademark applications, patent applications, and issued patents were searched for in separate databases using the USPTO search tools. Keywords, such as corporation names, product names, and inventor names were used in the patent search tool. Owner and Registrant company names and product keywords including “Juul Labs”, “Pax Labs” and “Ploom” were used to search the USPTO’s Trademark Electronic Search System (TESS). Published patent applications were searched using the Patent Application Full-Text and Image Database (AppFT) and issued patents were searched using the Patent Full-Text and Image Database (PatFT) of the USPTO. The AppFT and PatFT databases were searched using the keywords “IN/Monsees AND IN/Bowen” to reflect that both principals were named among the inventors on the issued patents and published applications, respectively. The “Electronic Cigarettes” section of the “Smoking and Tobacco Use” module [26] of the CDC’s website was monitored between 2018 and 2020 for announcements and data relating to Juul Labs™ and its products. FDA announcements, guidance, and rulings relating to Juul Labs™ products were monitored by subscribing to FDA email notifications for any FDA activity relating to tobacco products, including announcements by the US FDA Center for Tobacco Products. CDC and FDA communications were included if it identified Juul Labs™ by name or was related to a Juul Labs™ product.

The Delaware Division of Corporations [27] reports public information about companies incorporated in Delaware. Keywords “Juul,” “PAX,” and “Ploom” were used with DDC search tools to locate documents potentially related to Juul Labs™ and its affiliates.

Published research literature related to Juul® products was identified using Rochester Institute of Technology library search tools, subscription based databases, and publicly available databases. The word “Juul” was used in conjunction with a filter that returned only peer reviewed journal articles. Articles were assessed for relevance to this work by review of the abstract and conclusions. Articles deemed relevant were reviewed in more detail.

The Truth Initiative [28] and Tobacco Free Kids [29] are non-profit organizations that produce public information campaigns with facts about tobacco companies and nicotine use. Data from both organizations’ websites was captured and used in this work. While the Truth Initiative and Tobacco Free Kids are anti-smoking marketing tools, the campaigns cite government agencies and research institutions as well as their own surveys administered to youth. Data from both organizations were accepted as reliable and factual.

The Juul Labs™ retail websites were monitored between 2018 and 2020. Changes in available products were documented. The internet archive tool *Way Back Machine* [30] was used to review the limited number of past versions of retail websites which had been archived. Two source authentication was used for data captured from retail websites, both sources are cited in results.

In 2005, Adam Bowen and James Monsees presented their Master’s thesis for Stanford University’s product design program [16]. The presentation was uploaded to the Juul Labs™ YouTube channel on February 27, 2019. On April 22, 2019 the video was archived using *youtube-dl* [31], a program used to download videos from YouTube. The program was installed and run on a Linux machine. Once it was installed, the command ‘youtube-dl URL’ was run where “URL” was the YouTube video link. The video download was archived in a repository. It was attempted to obtain a copy of the written thesis. The authors names were used as keywords to search the ProQuest Dissertations and Theses database [32] and Stanford’s catalog and online institutional repository [33]. Emails were sent to the library at Stanford, the manager for mechanical engineering design at Stanford, and the Stanford Design Program Administrator. None of the contacted parties provided a copy of the thesis.

Newspaper articles from CNBC, The Verge, TechCrunch, Forbes, The NY Post, and Bloomberg were used as sources for this work. Articles were located using keywords regarding specific events surrounding Juul Labs™. Data from reputable periodicals were used. Two source authentication was used for most popular press articles. Both sources are cited in results where applicable.

## 2.2. Data Sequencing and Event Counting

Relevant facts and perspectives gathered from the sources were entered into a table of findings, placing events in chronological order with a concise description of each along with a short event title, classification (e.g. corporate event, milestone, trademark, patent application, issued patent, US Regulation, US State Regulation). Each document source was included as a single record in the findings table, while multiple data facts were extracted from each record. For example, each SEC filing was recorded as a single record in the findings table, but contained multiple facts including company name changes, executive officers and board membership, equity and debt placements, and private investor counts. Published patent applications were placed in the table based on their publication date, issued patents based on their issue date, and trademark applications based on their filing date. The title, abstract, claims, document images, and full text were assessed to determine if applications and patents were original or divisions or continuations of previous filings. Details of patent prosecution, issuance, division, continuation, extension, maintenance, and re-issue are not reported here. Data from published research articles were placed on the timeline based on the publication date of the paper. Changes to retail websites were given a general timeframe and each event on the timeline was approximate. News articles that described a change in the retail website, including change in product availability, were used to infer an approximate timeframe a change was made by the company. If a timeframe was given by the article, that date was used to place an event on the timeline otherwise the publication date of that article was used. Adam Bowen and James Monsees thesis work was placed on the time line based on the time interval they were reported to

have been in school for their Masters work. Data gathered from the presentation video was placed on the timeline in the year the presentation was given [17].

### 2.3. Data Interpretation

After the data were compiled by date, each item was sorted into one of eleven categories: corporate events, influence, research literature, market, patents (issued), patent applications (published), milestones, trademark applications, product development, U.S. Regulation, and State Regulation. Regulations outside the USA were not included. While partial data were collected for U.S. State regulatory actions, state-level data was not presented herein, as it was found to be challenging to ensure completeness, and dynamically changing. This paper presents and interprets data from the Corporate, Patent Application, U.S. Regulation, Milestones and Trademark Application categories. Data from the remaining categories are deferred to a future work.

### 2.4. Data Exclusion

Trademark applications identified using TESS were disambiguated and trademarks or wordmarks not related to the field of use of electronic cigarettes and vaporizers were excluded. For example, the keyword “JUUL” was, at one time, associated with custom clothing made by a designer having the surname “Juul” and a company named “Arx Pax Labs” was disambiguated from “Pax Labs.” These unrelated search results were excluded from data reported here. The company names associated with trademark filings were searched using the SEC EDGAR search tool and a generic internet search engine. If no evidence could be found linking key persons or company addresses to Juul Labs™, that data was not considered for this work. Issued patents and published patent applications resulting from USPTO searches were reviewed to determine whether each patent or application was related to a Juul Labs product or if the reference was to Juul Labs™ by a third party as part of a prior art citation. Any documents which did not appear to be assigned to Juul Labs™ or any of its affiliates, are not presented in this work. Data from non-reputable sources, such as a blog, was not included in this work if the piece of data could not be authenticated by a second source.

## 3. Results

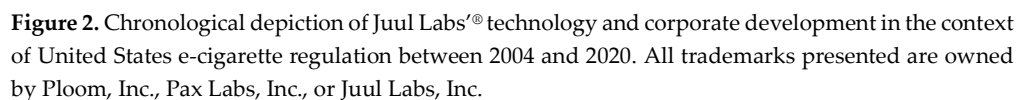
Figure 2 depicts the development of Juul Labs® technology and corporation, and its predecessor companies in the context of United States e-cigarette regulation between 2004 and 2020. The timeline is presented in the context of three major “eras” of focus: “MS Thesis. Tobacco”, “Product Development focused on Loose Leaf Tobacco and Marijuana”, and “Product Development Focused on Nicotine E-liquids.”

The nineteen “Corporate Filings & Events” illustrated in Figure 2 are composed of six DDC filings, ten SEC filings related to exempt offerings of securities, and three events documented through literature citations. While many activities occur within privately held companies which are never published, the DDC and SEC filings provide fixed points in time at which historical events related to the company can be documented.

The twelve “US Regulation” results presented in Figure 2 reflect FDA and CDC notices, activity reported by the US Congress legislation tracker, the Federal Register, and published literature. While some “first of a kind” state regulatory actions are presented in the following text, state actions are not illustrated in Figure 2.

The sixty four “Monsees and Bowen Patent Application” results presented in Figure 2 document the history of publication dates of each application. Patent applications are published by the USPTO one year after the application filing date, whether or not a patent has been issued. Patent prosecution often takes longer than a year, so applications are often the earliest published document which provide details regarding inventions and emergent technology. All 64 patent applications shown here included both Bowen and Monsees among the list of inventors. Of those 64 applications, there were 27 unique application titles, and the remaining 37 publications typically reflected divisions, continuations and subsequent prosecution of earlier applications. The application date of the 27 initial





Eighty seven trademark applications were determined to be associated with Juul Labs, Pax Labs, and Ploom. Many of the applications consisted of word mark applications, with re-filings to address changes in the scope of goods and services associated with various marks. Only three of the seventy four word mark filings found are presented in Figure 2, in the interest of brevity, while all symbolic trademarks are shown in the month and year of the initial filing. Cancellation of symbolic trademarks is indicated in the month and year of cancellation by virtue of a red circle overlaid on the trademark..

At least fifty five patents have been issued which are in some way affiliated with Ploom, Inc., Pax Labs, Inc., Juul Labs, Inc., Adam Bowen, or James Monsees. Of these, there were 23 design patents protecting ornamental design features of the companies' products, with the remaining 32 utility patents protecting underlying technologies.

Further details of the corporate events, patent applications, US Regulations, and trademark applications depicted in Figure 2 are presented as a historical summary to facilitate subsequent discussion.

### 3.1. MS Thesis Era

The first era, during 2004-05, reflects graduate master's degree collaboration by Juul Labs™ founders Adam Bowen and James Monsees. This collaboration resulted in the 2005 milestone event where they presented their idea for an electronic nicotine delivery system in their 2005 thesis presentation [16] at Stanford University, claiming that they set out to design for social change. They recognized that cigarette smoking had become socially delinquent and wanted to turn their tobacco product into a "luxury good," not just a drug delivery device [16]. They conducted market research by asking cigarette smokers what they loved about smoking and characterized these as attributes their device must have. They also asked smokers what they did not like about smoking and characterized these items as qualities their device must not possess. The creators also avoided using nicotine iconography, a different approach than many e-cigarette makers [16].

### 3.2. Loose Leaf Tobacco Era

The second era, beginning in 2006 and continuing into 2013, saw the founders incorporate their first companies and focus much of their product development effort broadly in the field of loose leaf tobacco and marijuana consumables.

The founders applied for word mark protection of "Ploom" on Jul 20, 2006 with the USPTO for goods and services related to "*electric vaporizers for the vaporization of tobacco*" (USPTO SN 78934325).

Juul Labs, Inc. and Ploom Investment, LLC filed incorporation papers on March 12, 2007 (DDC File Number 4315504) and May 30, 2007 (DDC File Number 4361140), respectively, with the Delaware Division of Corporations.

The first joint patent application for a "Method and System for Vaporization of a Substance" (USPTO Patent Application US 2007/0283972 A1) by James Monsees and Adam Bowen was published on Dec 13, 2007, based on a utility patent application which had been filed on Jul 11, 2006, which in turn, relied upon the provisional application No. 60/700,105 filed on July 19, 2005. Since the first application claimed priority based on a provisional application from 2005, it is apparent the invention was related to the pair's graduate studies. Next, Paax, Inc. filed as a Delaware Corporation on Jan 29, 2008 (DDC File Number 449618).

On April 15, 2009 (and subsequent April 20, 2009 notice of action) the FDA ordered that a shipment of NJOY e-cigarettes be denied entry to the US under the Federal Food, Drug, and Cosmetic Act. NJOY had imported and distributed such products in the US since 2007. On June 22, 2009 the US Family Smoking Prevention and Tobacco Control Act was signed into law [34]. This law did not specifically include electronic nicotine delivery systems (ENDS). In response, NJOY filed suit against the FDA questioning whether "Congress has authorized the Food and Drug Administration ("FDA") to regulate e-cigarettes under the drug/device provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 351 et seq., or under the Family Smoking Prevention and Tobacco Control Act of 2009 (the "Tobacco Act"), Pub. L. 111-31, 123 Stat. 1776".

Meanwhile, Juul continued to develop innovative technology related to loose leaf tobacco. Three additional patent applications were published in 2009, including "Aerosol Devices and Methods for Inhaling a Substance and Uses Thereof" (US 2009/0151717 A1) claiming priority of provisional application No. 61/014,690 filed on Dec. 18, 2007, and "Method and System for Vaporization of a Substance" which consisted of two application publications (US 2009/0260641 A1 and US 2009/0260642 A1) as divisions of application No. 11/465,168 filed on Jul 11, 2006, which in turn

claimed priority of the same provisional application No. 60/700,105 filed on Jul 19, 2005 described above. The '641 and '642 applications both listed Ploom, Inc. as the assignee.

On December 7, 2010 the federal court of appeals ruling (*Sottera, Inc. dba NJOY v. FDA*, 627 F.3d 891 [D.C. Cir. 2010]) [35] set a precedent giving the FDA authority to regulate ENDS devices and consumables under the Tobacco Act and not under the FDCA. The court ruled that derivatives of tobacco were to be regulated as a "tobacco product" unless "marketed for therapeutic purposes," in which case they would be regulated as drugs and/or devices [35].

On May 6, 2011 Ploom, Inc. filed their first notice of exempt offering of securities with the US Securities and Exchange Commission for \$3,330,163 in equity and options, having sold \$3,230,163 to 5 investors as of the filing date (SEC AN 0001520049-11-000001). James Monsees and Adam Bowen were listed as the sole executive officers, with a board comprised of Bowen, Monsees, Tom Dykstra (Tao, LLC) and Riaz Valeni (Ploom Investment LLC).

In December 2011, Ploom filed an application for the stylized logo shown in the lower middle of Figure 2. While Pax Labs incorporated in Delaware in 2008, their first trademark applications did not occur until 2012. In March and May 2012, the company filed for word mark protection on "Pax" for goods and services related to "Electric vaporizers for the ingestion and inhalation of [tobacco and other] herbal matter" (USPTO SN 85615996 and 85616035). In the interest of brevity, only the first occurrence of word mark applications for company names are showing in Figure 2.

### 3.3. Nicotine E-Liquid Era

The transition from a focus on loose leaf tobacco (Era 2) towards nicotine e-liquids (Era 3) appears to have begun mid-way through the year 2013 and included several important trademark and patent applications and investments. After a decade of studying vaporization of loose-leaf botanicals, Bowen and Monsees shifted their focus to nicotine salts, an e-liquid ingredient that supposedly gives a strong nicotine rush to users, vaporized in an elegant, sleek vaporizer that evokes a "ritual", similar to that of a traditional cigarette [36,37].

Two patent applications titled "Low Temperature Electronic Vaporization Device and Methods" were published on Feb 21, 2013 (US 2013/0042865 A1) and Nov 28, 2013 (US 2013/0312742 A1) both claiming priority of provisional application No. 61/524,308 filed on Aug 16, 2011. These two applications referred to a device to "generate an aerosol for inhalation by a subject heating a viscous material that can have a tactile response in the mouth or respiratory tract." These two documents disclose many novel features which would subsequently become associated with the innovative product known as the Juul electronic cigarette.

The stylized X trademark was filed on Aug 27, 2013 (USPTO SN 86049092) and is illustrated in Figure 2. Additional word mark applications filed in 2013 included POTRERO (USPTO SN 85903278) subsequently cancelled on Dec 4, 2020, KICK-ASS MINT (USPTO SN 85903346) cancelled on Jul 17, 2020, ROCKET (USPTO SN 85903339) cancelled on June 26, 2020, JAYBIRD (USPTO SN 85903297) for goods and services related to processed tobacco pods, and BLEND X (USPTO SN 85903302) for pipe tobacco used in electric vaporizers.

The transition towards electronic cigarettes accelerated in 2014 when Japan Tobacco International [38] entered into an exclusive long-term cooperation agreement whereby JTI would commercialize PAX Labs™ ENDS device to sell outside of the United States [38]. JTI acquired the Ploom product line, intellectual property related to the Ploom device, including the Ploom trademark, and a minority stake in PAX Labs™[38,39]. Financial details of the agreement were not released.

One new patent application title, "Multiple Heating Elements with Separate Vaporizable Materials in an Electric Vaporization Device", was published in 2014 (US 2014/0366898 A1). This application discloses a two compartment vaporizer wherein the material being vaporized in each compartment could be the same or different, and the vaporization temperature of each compartment could be the same or different. Dependent claims describe the presence of wicking material, additional compartments and extensions of the core concepts.

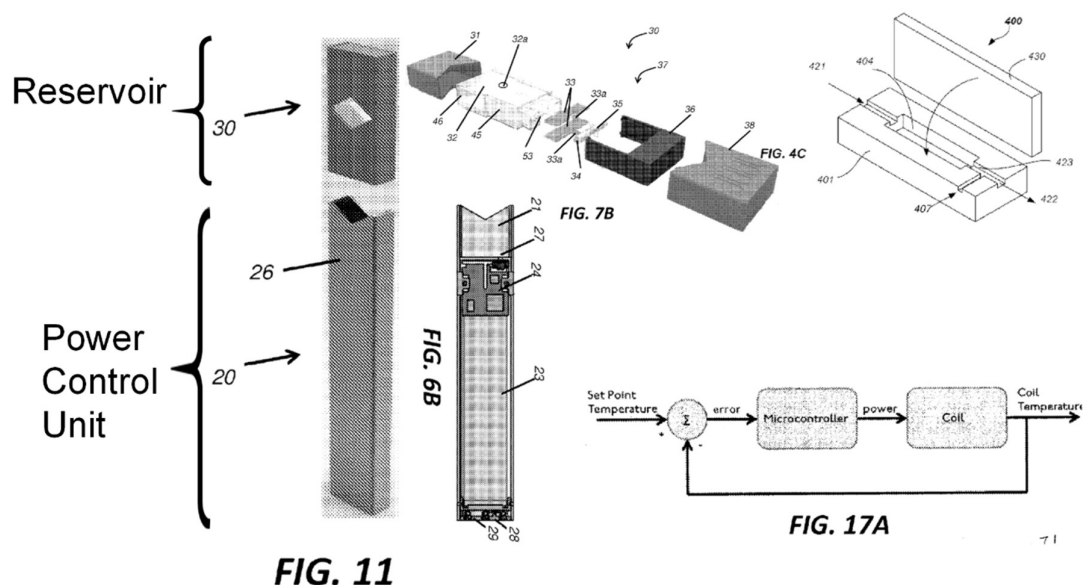


Applications for the word mark “JUUL” were filed on January 1, 2014 and August 26, 2014 for goods and services related to nicotine-based liquid, refill cartridges, chemical flavorings and electronic cigarettes (USPTO SN 86156947 and 86377625, respectively), followed by the stylized PAX2 trademark on August 26, 2014 (USPTO SN 86377639) and an updated PAX2 word mark (USPTO SN 86377625).

2015 was a busy year, highlighted by the milestone event of Juul electronic cigarettes entering the US market. Pax Labs filed two exempt offerings of securities in 2015 (changing the name from Ploom Inc. to Pax Labs Inc) on April 7 and June 4, 2015 (SEC AN 0001520049-15-000004 and 0001520049-15-000005, respectively). Adam Bowen and James Monsees were listed as the sole executive officers, with an expanded board comprised of Bowen, Monsees, Nicholas Pritzker (Tao, LLC), Riaz Valeni (Ploom Investment LLC) and Harold Handelsman (c/o PAX Labs). The first filing disclosed a \$25 million equity round, with \$6.5 million sold to 4 investors at the time of the filing and the amended filing, just two months later, increased the equity sought to \$46,685,837 already sold to 54 investors.

The application titled “Vaporization Device Systems and Methods” (US 2015/0208729 A1) was published on June 30, 2015 and referred to three earlier applications dating as early as Dec. 23, 2013. This application described the essential embodiments of the Juul electronic cigarette and disclosed a sophisticated feedback for coil temperature control, pressure sensor activation, charging circuitry, user feedback, coil and wick geometry, preferred materials, and detailed assembly instructions.

Images from the ‘8729 application were extracted and annotated and are presented in the composite Figure 3. The numerical annotations reference the static description of the invention as disclosed in the application. It is instructive to compare the annotated photographs of Figure 2 against the patent application graphics of Figure 3. Virtually every novel aspect of the Juul e-cig introduced in 2015 is documented in this published application. It was clear, as early as June 2015, this product contained significant advances in technology in comparison to other e-cigs in the market at the time.



**Figure 3.** Annotated composite of multiple figures presented in US Patent Application 2015/0208729 A1 published on June 15, 2015.

One of the relatively few issued patents not jointly identifying Bowen and Monsees as co-inventors was invented by Bowen and Xing, titled “Nicotine salt formulations for aerosol devices and methods thereof,” filed in October 2014 and granted in December 2015 [40] claiming priority of two provisional applications filed in 2013. The nicotine salt formula is one aspect of what Juul Labs™ advertises to make their product innovative. Nicotine salts are found in leaf-based tobacco.

According to Juul Labs™[37], this constituent creates a unique smoking experience, similar to smoking a combustible cigarette.

The stylized JUUL trademark application was filed in July (USPTO SN 86683423). Additional word mark applications filed in 2015 included MAKE THE SWITCH TODAY (USPTO SN 86541730) for good and services related to electronic cigarette refill liquids, chemical flavorings and cartridges filled with such liquids, PAX LABS (USPTO SN 86542944) subsequently abandoned on December 10, 2018, and BRUULÉ (USPTO SN 86561259), TABAAC (USPTO SN 86561249), FRUUT (USPTO SN 86567416), MIINT (USPTO SN 86567410) all of which were abandoned months later on December 8, 2015.

On May 10, 2016, six years after the *Sottera, Inc. dba NJOY v. FDA* ruling, the FDA published the rule “Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products,” which asserted the agency’s regulatory authority over e-cigarettes. This rule, which had been originally proposed by the FDA on April 25, 2014, went into effect on August 8, 2016 and included the requirement of premarket data or substantial equivalency requests for all newly regulated products (such as e-cigarettes not already commercially marketed in the US as of February 15, 2007) [41]. Following this rule, regulation of e-cigarettes in the US began to increase. Meanwhile, 14 additional patent applications were published in 2016 and 2017, the details of which foreshadowed the evolution of Juul products.

Pax Labs (formerly known as Ploom, Inc) filed another notice of exempt offering of securities with the SEC in 2016 for an offering amount of \$29,999,997 (\$4,378,778 sold to 2 investors as of 12/28/2016) as equity. This filing reported four executive officers: Adam Bowen, James Monsees, Timothy Danaher and Tyler Goldman while retaining the same board members reported in the 2015 filings (SEC AN 0001520049-16-000008).

A potentially transformative patent application entitled “Calibrated Dose Control” (US 2016/0157524 A1) was published on Jun 9, 2016 and claimed reference to two previous unpublished applications filed as early as Dec 5, 2014. This application describes “*Methods and vaporizer apparatuses that estimate, measure and/or predict the amount of vapor and/or material (including active ingredients) released by the vaporizer apparatus...*” This application appears to be the first evidence of an invention to quantify and report the dose of substances, such as nicotine, delivered from an electronic cigarette to the mouth of the product user. The remaining seven applications published in 2016 represented continued prosecution, divisions and continuations of previously described applications.

A stylized trademark application for the Juul geometrical shape (USPTO SN 87154451) was filed in 2016, along with a stylized version of Ploom Tech (USPTO SN 79186300), both illustrated in Figure 2. Additional word mark applications filed in 2016 included AETHER (USPTO SN 86914659), ERA (USPTO SN 86966302), PAX3 (USPTO SN 87119540), PAX 3 (USPTO SN 87119522), ERA (USPTO SN 87134043), SIMPLECLICK PODS (USPTO SN 87179108), SIMPLECLICK (USPTO SN 87178892), SESSION REHASH (USPTO SN 87179115), DYNAMIC MODES (USPTO SN 87284439 and 87981565), all of which would be abandoned no later than June of 2020. Many of these word marks provide hints into emerging technologies being investigated by Juul, which would not become publicly evident until two or three years later, when corresponding patent applications were eventually published, 12 months after the initial patent application filing date.

By the end of 2017, Juul Labs™ led all U.S. e-cigarette sales capturing about 13% of the market [42]. The Juul™ e-cigarette had become “one of the fastest-growing consumer products in history” according to *Fast Company* [17]. When the founders of PAX Labs launched the Juul® e-cigarette in 2015, they approached it as launching a new technology, not a drug delivery system. They used a traditional start-up narrative: “identify the needs, scale the solution” [17], which means the company was founded on novel innovation to fulfill specific consumer needs with the goal of making a rapid transition from a small start-up company to securing a major market position.

The company filed two SEC exempt securities offering notices during 2017. The first was an amendment to the 2016 filing by Pax Labs (formerly Ploom, Inc.) for increasing the offering amount

to \$54,999,995 (with \$54,999,995 sold to 34 investors as of 3/17/2017) as equity (SEC AN 0001520049-17-000001). This filing added Ashley Gould to the slate of executive officers, while the board remained the same as in 2016. The second filing by Juul Labs, Inc. (formerly Ploom, Inc. and Pax, Inc.) was for an offering amount of \$150,000,000 (with \$111,500,000 sold to 23 investors as of 12/19/2017 and the date of the first sale taking place on 12/4/2017) as convertible note (SEC AN 0001520049-17-000003). Kevin Burns replaced Tyler Goldman as Chief Executive Officer while Zachary Frankel and Ho Young Huh (c/o Juul Labs) were added to the board of directors.

Four novel patent applications were published in 2017, along with applications which appeared to be continued prosecution of earlier invention filings. All four applications centered on enhancing and protecting the product technologies making Juul's products distinctive in the marketplace at the time. The application "Cartridge for Use with a Vaporizer Device" (US 2017/0035115 A1) expanded upon many of the features and attributes described in Figure 3, and articulated the importance of the cannula labeled as the "Output" in Figure 1. Similarly, the application "Securely Attaching Cartridges for Vaporizer Devices" (US 2017/0231282 A1) expanded upon many of the attributes previously described in Figure 3, including the rectangular shape, clearances, electrical and magnetic connections between the reservoir and the PCU. This application claimed several specific embodiments regarding the coil, wick, and liquid storage reservoir that were partially disclosed in earlier applications, such as those illustrated in Figure 3, but had not been specifically entered as claims. The "Vaporization Device with Lip Sensing" (US A1) describes *"vaporizers incorporating capacitive lips sensing to regulate the temperature of the vaporizer, including transiently boosting the temperature..."* documenting further advancements in the companies' technologies related to feedback control of temperature, and presumably, dose delivered to the user. The application "Systems and Methods for Aerosolizing a Smokeable Material" (US 2017/0181468 A1) was assigned to Pax Labs, and continued the technology development effort related to botanicals.

A stylized trademark application for the Juul Labs corporate logo (USPTO SN 87657660) was filed in 2017, illustrated in Figure 2. Building upon their 2015 word mark MAKE THE SWITCH TODAY, the company filed another word mark application for JUUL. MADE FOR SWITCHING (USPTO SN 87369494) on March 13, 2017. Both of these word mark applications could have signaled Juul's clear intent to begin promoting their product as an alternative to combustible cigarettes.

The popularity of the Juul® e-cigarette raised concerns among lawmakers, prompting the US government to act in late 2018 when the FDA commissioner proclaimed that youth e-cigarette use was at "epidemic proportions" [43]. In September 2018, the FDA began to issue thousands of warning letters and civil money penalty complaints to retailers who were illegally selling Juul® and other e-cigarette products to minors [44,45]. The companies were given 60 days to demonstrate steps they would take to keep their products out of the hands of minors [19]. The FDA also requested information related to marketing practices from Juul Labs™ and several other e-cigarette manufacturers [19,44]. A month later, in October 2018, the FDA raided Juul Labs™ headquarters in San Francisco with a surprise onsite inspection [19,46]. During this inspection, the FDA obtained thousands of documents from Juul Labs™ related to marketing [46]. The FDA was concerned about Juul® products' role in the rise of youth tobacco use [44]. Shortly after the FDA's unannounced visit to Juul Labs™ headquarters, the FDA gave the company and four other popular e-cigarette device makers an ultimatum. In November 2018 the FDA took the first large step in the regulation of electronic cigarettes by announcing a plan to limit the sale of flavored cartridge-based e-liquids to smoke shops and online [43]. The agency also released their plan to implement age-verification guidelines for online sales [18].

During 2018 Juul Labs™ appeared to implement a plan to pre-empt regulation that would likely affect sales. Juul Labs™ rebranded from a company characterized by bright colors, contemporary graphics, and young people using Juul® e-cigarettes [47] to adopt a medicinal ambiance [48]. Juulpod™ packaging was altered to include a nicotine warning on the front and the nicotine strength listed in much larger, prominent font. Further, Juul Labs™ renamed many of their flavors, replacing friendly adjectives like "cool" with a name that describes flavor objectively. Juul® Lab's also deleted all content from their social media accounts and released TV commercials directed at an older

audience, with an emphasis that the product is for established cigarette users who want to stop smoking [48]. In late October 2018, Juul Labs™ pulled their “child friendly” flavored products, including all e-liquids with flavor additives other than tobacco and menthol flavor, from the shelves of physical retail stores, excluding 18+ smoke shops [49], noted as a milestone event on Figure 2. It should be noted that Juul’s decision to pull flavors in October 2018 preceded the formal FDA action in November 2018 which placed restrictions on the sale of flavored cartridge-based e-liquids. In the fourth quarter of 2018, Juul Labs™ net revenue reportedly dropped for the first time in several quarters, during the same timeframe the FDA limited the sale of flavored e-liquid products [50].

Juul filed another exempt offering notice for an offering amount of \$1,250,000,000 (with \$650,000,000 sold to ten investors as of August 19, 2018, with the first date of sale on June 26, 2018) as equity (SEC AN 0001520049-18-000001). Gerald Masoudi was added as Chief Legal Officer and Burns replaced Huh on the board. Juul was valued at an estimated \$38 billion in late 2018 when the tobacco giant Altria invested \$12.8 billion for a 35% stake in the company, announced on December 18, 2018 [51]. The details of the transaction between Altria and Juul were not disclosed. It was not clear what portion of the \$12.8 billion investment went to buying out previous private shareholders, and what portion represented issuance of shares under previous SEC filings. Clearly, the Altria investment was larger than the sum of all SEC debt and equity placements identified herein.

Twenty two Juul patent applications were published in 2018. Most of these applications were related to continued prosecution of previous submissions, including eleven applications related to the core technology “Vaporization Device Systems and Methods”, three applications related to the “Vaporizer Apparatus”, three applications titled “Cartridge for Use With a Vaporizer”, and two applications for “Control of an Electronic Vaporizer.” One application, “Securely Attaching Cartridges for Vaporizer Devices” (US 2018/0070646 A1) was related to eight preceding applications, as early as Dec 23, 2013, and addressed challenges faced by many electronic cigarette manufacturers – to achieve a mechanical and electrically strong connection between the removable reservoir and the power control unit of the device.

The remaining two applications published in 2018 are worthy of mention. The first was titled “Leak Resistant Vaporizer Device” (US 2018/0077967 A1) claimed priority of a previous application filed on Sep 22, 2016 and describes *“leak-resistant vaporizer cartridges and/or apparatuses adapted for use with oil-based vaporizable materials including cannabis oils ...”* which suggests the era of cannabinoids may be resurrected in Juul’s future. The second application, “On-Demand Portable Convection Vaporizer” (US 2018/0000160 A1) was related to two earlier applications dating back to Jun 16, 2016, and describes *“... heating air drawn through an oven chamber to a predetermined or selectable vaporizing temperature to vaporize a material (e.g., loose leaf plant material, etc.) that is held in the oven chamber ...”*. This application indicates continued interest on the part of Juul to develop technology for vaporizers of loose leaf botanicals, hearkening back to the founders’ graduate studies.

Five stylized trademark applications filed in 2018 are illustrated in Figure 2, and included PAX and PAX3 trademarks (USPTO SN 88234424 and 87119540), along with two Juul hexagons (USPTO SN 88053003 and 87851490) and a line drawing of a JUULPOD (USPTO SN 88053010). Two word marks filed in 2018 remained live as of the end of December 2020: JUULING (USPTO SN 87851553), DYNAMIC MODES (USPTO SN 88886595), while five additional word marks filed during the year 2018 were subsequently abandoned within 18 months: JUULPODS (USPTO SN 87871392), JUUL VAPOR (USPTO SN 87871384), JPODS (USPTO SN 87929793), JUUL TALK (USPTO SN 87956869), and JUULMELIER (USPTO SN 87657631). In particular, the word mark applications for DYNAMIC MODES and JUUL TALK could be interpreted as foreshadowing future corporate intentions.

The 2019 Juul milestones of “introducing a reduced nicotine concentration e-liquid” to the market and “eliminating flavors” other than tobacco and menthol are shown in Figure 2. Both of these milestones could be reasonably attributed to the FDA regulatory actions during 2018. Two significant federal actions occurred in 2019, including addition of a prominent nicotine warning on the front of e-cigarette products, and the FDA issuance of a warning to Juul Labs for marketing unauthorized modified risk tobacco products. On November 17, 2019, Massachusetts became the first state to ban the sale of flavored e-cigarette products other than tobacco and menthol flavor [52],



while hundreds of localities across the United States have since formed their own legislation restricting sale of flavored e-cigarette products [52].

In early 2019, as recent FDA regulations on e-cigarettes were being enforced, Juul Labs™ worked to expand its team. The company hired a former Cardinal Health executive to lead a team tasked with creating partnerships between Juul Labs™ and “health plans, providers, self-insured employers, and the public sector” [53]. The “enterprise markets team” included 17 employees as of March 2019.

Juul Labs filed another notice of exempt offering of securities in the amount of \$325,000,000 (with \$325,000,000 sold to four investors as of the Aug 8, 2019 filing date with the first sale reported as August 2, 2019) as equity and debt (SEC AN 0001520049-19-000003). Less than two weeks later, Juul amended the securities filing to increase amount to \$800,176,874 (with \$785,176,874 sold to 14 investors as of the Aug 30, 2019 filing date) as equity and debt (SEC AN 0001520049-19-000004). In the amended 2019 filing, the executive officer positions for James Monsees and Adam Bowen were clarified to be “Chief Product Officer” and “Chief Technology Officer” respectively. No additional changes were reported to the executive officers or board membership.

Six patent applications were published in 2019. Of these, two applications present insights into technologies which were not readily apparent in Juul’s commercial products at the time. The remaining four applications represented continued prosecution of earlier filings with the USPTO.

One important application titled “Electronic Vaporizer Sessioning” (US 2019/0158938) claimed priority of a previous application filed on Nov 22, 2011 and provides insight into Juul’s technology development plans for “*Devices, systems and methods for electronic vaporizer sessioning ...*” They described a vaporizer device (such as an e-cigarette) connected to a user device (such as a mobile phone or computer) via the user interface of an application. The publication described how the software app could compare an individual’s actual usage with their preferences during a time interval, and determine settings for the vaporizer device aligned with the user’s preferences. This application foreshadows capability of the Juul product line enabling users to manage their level of product use.

Another significant application, “Vaporization Device Control Systems and Methods” (US 2019/0069599) described the underlying technologies which would enable the sessioning methods described in the previous paragraph. The application described “... *methods for controlling the power applied to a resistive heater of a vaporization device by measuring the resistance of the resistive heater at discrete intervals. Changes in the resistance during heating may be used to control the power applied to heat the resistive heater during operation...*” and vaporization devices configured to employ those methods. This document describes increasingly sophisticated feedback control logic allowing the power control unit to limit the rate and amount of aerosol generated in the oven.

Juul filed a significant RACS trademark application on August 6, 2019, as shown in Figure 2 (USPTO SN 88568223). This trademark application described the goods and services as “*Promoting awareness of new authentication and identification technologies to prevent retail sale of nicotine products to underage consumers ...*” and development of corresponding voluntary standards. This trademark filing appeared timely in light of recent regulatory actions and the national spotlight on the youth e-cigarette epidemic. It also provides the research community with a clear indication of potential future technology and market innovations by the company.

A second stylized JUUL trademark application was filed in February (USPTO SN 88052998) expanding the goods and services to include “*Carrying cases, holders, and protective cases featuring power supply connectors, adaptors and battery charging devices adapted for use with handheld electronic devices, namely, electronic cigarettes*” and “*Printed materials and publications, namely, user manuals, booklets, and brochures all in the field of electronic cigarettes and vaping technology.*”

Additional word mark applications filed in 2019 included JUULPODS (USPTO SN 88289543), JUULPOD (USPTO SN 88630166), MAKE THE SWITCH (USPTO SN 88480564), MAKE THE SWITCH (USPTO SN 88484337 subsequently abandoned in October 2020), JUUL C1 (USPTO SN 88524986), JUUL C2 (USPTO SN 88524992), JUUL C3 (USPTO SN 88663906), THE ALTERNATIVE FOR ADULT SMOKERS (USPTO SN 88524012), and JUUL PASS (USPTO SN 88550676). Many of these word mark applications claim goods and services related to downloadable software, remotely



setting and adjusting vaporizer power parameters, “transmitting and reporting information relating to the location, movement, proximity, departure and arrival of individuals and objects” and a variety of other technological innovations which might be forthcoming in future months and years.

On February 28, 2020, the US House of Representatives passed a bill titled Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act of 2020. If made law, the bill would revise “requirements related to the safety, sale, and advertisement of tobacco products, including electronic nicotine delivery systems,” including “prohibit[ing] the use of flavored products in an electronic nicotine delivery system”[54]. On March 2, 2020, the bill was received by the US senate and read twice. The US Congress bill tracker reported the bill died at the conclusion of the 116<sup>th</sup> congress (2019-2021), having never been passed by the US Senate. Meanwhile, New York, New Jersey, and Rhode Island passed their own statewide laws to ban flavors in 2020 [55].

Juul filed one exempt SEC offering during 2020 for \$721,555,937 (with \$721,555,937 sold to 20 investors as of the Feb 7, 2020 filing date, and the first date of sale reported as Feb 3, 2020) as a combination of debt and equity (SEC AN 0001520049-20-000001). As of this filing, K.C. Crosthwaite had replaced Kevin Burns as CEO and board member and Saurabh Sinha replaced Timothy Danaher as Chief Financial Officer.

Five applications published in 2020 are of particular note and demonstrate Juul’s continued technology development in the areas of smart electronic cigarettes and heat-not-burn products. The first application published in 2020 appeared on Jan 2, 2020 and was titled “Connected Vaporizer Device Systems” (US 2020/0000143 A1) and described emergent technology being invented by the company. The abstract is a compelling summary of what may be expected from future Juul products. The abstract states:

*“A vaporizer system may include a vaporizer device communicatively coupled with a user device configured to control the functions and/or features of the vaporizer device. The vaporizer device may serve as a replacement for traditional combustible cigarettes. Accordingly, the user device may be configured to collect usage data from the vaporizer device and generate recommendations to enhance and/or expedite the transition from traditional combustible cigarettes to the vaporizer device. For example, the user device may provide puff coaching to enable a more satisfying initial experience. Alternatively and/or additionally, the user device may recommend pod types and/or puff patterns that are associated with a reduction in overall intake.”*

Of particular interest are the statements regarding technologies designed to enhance or expedite users switching from combustible cigarettes and/or reducing overall intake. Whether the company seeks approval for future products as a tobacco cessation therapy remains to be seen, however, this application establishes a clear path forward for such innovation.

This smart e-cigarette theme continued throughout 2020, including an application published on Nov. 12, 2020, titled “User Interface and User Experience for a Vaporizer Device” (US 2020/0352249 A1) which describes “... a device in communication with a vaporizer, can include one or more features related to control of functions and/or features of the vaporizer, identification of a cartridge and/or a vaporizable material in the cartridge, data exchange (either one-way or two-way) between a cartridge and a vaporizer with which the cartridge is engaged...”

Concurrently, Juul Labs remained focused on advancing technologies hearkening back to their corporate origins. The application titled “Cartridge-based Heat Not Burn Vaporizer” (US 2020/0037669 A1), assigned to Juul Labs, provides some indication of Juul potentially moving into the arena of heat-not-burn non-liquid vaporizable materials. The background, summary and description of the invention application focused primarily on loose-leaf tobacco and parts of tobacco leaves, with passing reference to additional broad categories of prescribed medicants and other plant-based smokeable materials such as cannabis, including “solid (e.g., loose-leaf) materials, solid/liquid (e.g., suspensions, liquid-coated) materials, wax extracts, and prefilled pods (cartridges, wrapped containers, etc.) of such materials.”

Juul continued to developed technologies associated with its relationship with JTI, the assignee of the application titled “Cartridge Used in a Smoking Device for Vaporization” (US 2020/0221759

A1) published on July 16, 2020, which resurrected an earlier related application from December 19, 2014.

Throughout 2020, Juul continued to protect aspects of its core electronic cigarette technology, with the application titled “Airflow Management for Vaporizer Device” (US 2020/0022417 A1) published on Jan. 23, 2020, disclosing several details of Juul’s sophisticated airflow management technology incorporated in the design of their trademarked and patented JuulPods™. The remaining seven applications represented continued prosecution of earlier filings with the USPTO.

Several word mark applications were filed between February 10 and December 14, 2020, including PAX 3 (USPTO SN 88838692) and PAXFINDER (USPTO SN 90381107) related to devices marketed for use with cannabinoids in some US jurisdictions, and PLOOM (USPTO SN 79281555) for goods and services related to vaporizers for a variety of tobacco consumables.

The word mark SIMPLECLICK (USPTO SN 88838697) was associated with many of the goods and services central to Juul’s traditional field of business, but interestingly added reference to “*flavorings other than essential oils*” and “*refill cartridges sold empty*.” While Juul’s prior products featured non-refillable pods this could indicate a future shift in product direction. The word mark application for ERA LIFE (USPTO SN 88945355) similarly declares several aspects familiar to Juul products, but adds references to “*refill cartridges sold empty*” and “*smokeless vaporizer pipes for the ingestion and inhalation of herbal matter*.” The word mark application for BEACON (USPTO SN 90381115) simply declares goods and services related to “*downloadable software for use with oral vaporizers and electronic cigarettes*.” This phrase takes on additional significance in the context of the RACS trademark file in 2019 and the several patents application published in 2020. The word mark BINGO (USPTO SN 88790625) was associated with goods and services related to near field communication technology programming and reading devices – such as might be needed to incorporate radio frequency identification into future products.

#### 4. Discussion

Public policy is often described as an iterative cycle of five steps including (1) problem identification and agenda setting, (2) policy formulation, (3) decision making and formal policy adoption, (4) policy implementation, and (5) policy assessment or evaluation. Before a policy is created by a governing body, some person or event must bring an issue to the forefront and garner the attention of public authorities. Policies cannot be formulated or adopted by decision makers until after an issue has been identified. Then, and only then, can policies be put into practice. When policies are in operation, a formal assessment process (for example a sunset clause on a policy) may be triggered, or a new issue may arise which was not foreseen by the policy, to begin the cycle again.

While systematic challenges prevent policy from being proactive, research does not need to be reactive. The process of studying patent, trademark and securities literature may permit regulatory research and agenda setting to become more proactive. Future work should both study solutions to eliminate the public health crises caused by e-cigarettes and develop procedures to avoid future emerging technologies from having such deleterious effects.

Portions of the policy cycle are evident in the timeline of Figure 2. Companies often anticipate regulatory actions before they are officially enacted, as seen with Juul’s preemptive October 2018 flavor milestone, presumably in an attempt to stave off the FDA’s November 2018 formal action. Conversely, regulatory action does not traditionally anticipate corporate technology innovation, but rather reacts to technology innovation. This reactive approach creates a significant time delay between the emergence of a new technology and regulatory response ... a classic example of which is the deeming rule. The Tobacco Act was passed in 2009, and was cited almost immediately by NJOY in defense against the April 2009 FDA action taken against them under the Food, Drug and Cosmetic Act (FDCA). The 2010 court decision led to FDA proposing the deeming rule in April 2014. The final deeming rule was not published until after public comment and response period in May 2016, and did not go into effect until August 2016. Thus, the steps of policy formulation and policy adoption spanned more than seven years, and all aspects of the pre-market tobacco application (PMTA)

requirements are still not implemented as of December 2020 – eleven years after the initial attempted FDA action under the FDCA.

We recognize that regulatory bodies are restricted by legislative authority and that tobacco regulations must be science-based. However, we propose that instead of waiting until new products enter the market, emergent regulatory science research questions can be identified by anticipating emergent technologies and laying the foundation for background research to shorten the time between product introduction and regulatory response.

The patent and trademark literature provide significant insights into company technologies which may inform future regulation. Consider, for example, the RACS, connected e-cigarettes, dose control trademark, and related patent applications. Clearly, technologies to curb under-age youth use of tobacco products are emerging. Technologies to limit the dose of nicotine or other substances are coming in the future. We should begin conducting research now to facilitate future regulations requiring access control and dose control technology implementations in all future tobacco products, possibly including combustible tobacco, heat-not-burn products and vaping products. For example, the invention disclosed in patent application “Calibrated Dose Control” (US 2016/0157524 A1) demonstrated companies have the ability to incorporate dosage limits into their product. This observation suggests immediate research is needed to established whether, and under what conditions, there exists a nicotine dose threshold during a specified time interval which inhibits addiction. Research such as [56] [57] lays the foundation for establishing a connection between the dose delivered to the mouth of the user and ultimate airway exposure and deposition ... opening the pathway to better understanding public health effects of proposed regulatory action from a mechanistic perspective.

5. Conclusions

Research funding agencies and their review panelists, particularly those focused on regulatory science, should specifically acknowledge and recognize the probative value of citations to patent, trademark, and SEC filing literature as a means of identifying emergent issues. Documents submitted to these robust government-curated archives undergo a rigorous review process in order to be published, even though the documents may not report findings of scientific research. These three document sources are clear technology indicators which provide insight into technology companies are developing and investing in. Thus, citations to such documents should be embraced as establishing the premise or “setting the agenda” for emergent regulatory science research questions.

Furthermore, the methods presented here can be used to identify key aspects of emerging technologies before products actually enter the market. If the existence of significant patent, trademark and SEC filings is accepted as a means of identifying potential emergent regulatory issues, then the contents of those documents provide valuable information about the technology development being pursued by commercial entities. Scientists could begin conducting research to understand critical parameters before products enter the market. Funded research on emergent core technologies could significantly reduce the time lag between problem identification, policy formulation, and policy adoption.

The traditional public policy cycle is reactive, not proactive. The methods presented herein permit the first two steps in the policy cycle, problem identification and policy formulation, to be undertaken proactively – dramatically shortening the elapsed time between problem identification and policy implementation.

Abbreviations

AN:	Access Number
CDC:	Center for Disease Control and Prevention
DDC:	Delaware Division of Corporations
e-cigarette:	electronic cigarette
EDGAR:	Electronic Data Gathering, Analysis, and Retrieval

e-liquid:	nicotine laden liquid used in electronic cigarettes
ENDS:	electronic nicotine delivery system
FDA:	Food and Drug Administration
JTI:	Japan Tobacco International
LLC:	Limited Liability Corporation
AppFT:	Patent Application Full-Text and Image Database
PatFT:	Patent Full-Text and Image Database
PCU:	power control unit
SEC:	Securities and Exchange Commission
SN:	Serial Number
TESS:	Trademark Electronic Search System
US:	United States
USB:	Universal Serial Bus
USPTO:	United States Patent and Trademark Office

**Author Contributions:** The authors' individual contributions included: conceptualization, S.E.S. and E.C.H.; methodology, S.E.S. and E.C.H. software, S.E.S. and E.C.H.; validation, S.E.S., E.C.H. and R.J.R.; formal analysis, S.E.S. and E.C.H.; investigation, S.E.S., E.C.H., and R.J.R.; resources, E.C.H. and R.J.R.; data curation, S.E.S. and E.C.H.; writing—original draft preparation, S.E.S. and E.C.H.; writing—review and editing, R.J.R.; visualization, S.E.S. and E.C.H.; supervision, E.C.H. and R.J.R.; project administration, E.C.H. and R.J.R.; funding acquisition, E.C.H. Please turn to the CRediT taxonomy for term explanation. All authors have read and agreed to the published version of the manuscript.

**Funding:** This work was supported by internal funds from Rochester Institute of Technology.

**Acknowledgments:** The authors acknowledge the assistance of Respiratory Technology Lab members Bryan Meyers, Qutaiba M. Saleh, A. Gary DiFrancesco and RIT Librarian Linette Koren.

**Conflicts of Interest:** None of the authors have any conflicts of interest to declare.

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