JULY 2021 PATENT LANDSCAPE REPORT

PREPARED FOR THE FOUNDATION FOR A SMOKE-FREE WORLD



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1 One Minute Read

This report offers an opinion on the patent landscape of heated tobacco, nicotine vapour, and smokeless tobacco technologies. The most striking insight is that patenting activities in developing and least-developed countries are not comparable to those in the developed world. Vast amounts of Africa, for example, are completely void of patent activity. This observation can be interpreted in different ways. If technology aimed at reducing the risk of smoking is not even protected in many parts of the developing world, this suggests that tobacco firms have no particular interest in making the potentially less harmful versions of their products available in these parts of the world. This can lead to further fragmentation and marginalisation within the sector. It can also mean that access to potentially reduced-risk products shows a sharp gap between the haves and have-nots. To the extent that these technologies are able to address tobacco-related health risks, future research should seek ways to motivate corporations to ensure the adequate dissemination of potentially less harmful versions of their products in these parts of the globe as well.

On the other hand, the fact that much of the developing world has been spared from patent protection could mean easier access to otherwise protected technology and easier technology transfer. Imitation may still be an option in these regions quite simply because there is no patent protection.

For us, the evident gap in patent protection between high- and low-income countries is one of the key takeaways of this report. How to motivate corporations to ensure access to potentially less harmful tobacco products is an important question to address in the future. After all, publicly traded corporations are under pressure to deliver shareholder returns. Could this be a genuine effort to advance corporate social responsibility?

- Across all technology spaces analysed, the leaders for patents published in the past 10 years include established tobacco companies such as Philip Morris International (PMI), British American Tobacco (BAT), and China National Tobacco Corporation (CNTC). These companies maintain the largest patent portfolios in the tobacco harm-reduction space, showing that developing new types of tobacco products that may be considered forms of tobacco harm reduction is a priority in their technology strategies.
- With respect to patent publications by tobacco companies in the past 10 years, there was a significant increase in numbers of patents published in technologies that could result in smoking-cessation medical devices or be applied to other therapeutic purposes. This indicates a shift in priority from selling recreational technology toward development and patenting of potentially more therapeutically oriented technology.
- Pharmaceutical companies, while active in the tobacco harm-reduction technology space, appear to be focused on pharmaceutical uses for nicotine, nicotine cessation therapies, and crop science related to the tobacco plant. The patent filings do not appear to indicate that pharmaceutical companies are entering the recreational nicotine space.

- Nicotine vapour technology is the fastest growing tobacco harm-reduction technology space in terms of patents published, with a compounded annual growth rate of 9.1%, double that of heated tobacco technology (4.1%) and about nine times that of smokeless tobacco technology (1.1%).
- The number of patents published for nicotine vapour technology per year overtook that of heated tobacco technology in 2020, showing that the technology space may be seeing some form of consolidation of technology ownership and moving away from its fragmented history. Patent activity is generally fragmented in each technology space.
- Geographically, China has the highest total number of patents published over the past 10 years, with 46,850 patents published. China also had the highest number of patents in heated tobacco technologies (22,956 patents) and nicotine vapour technologies (15,929 patents).
- The United States is second in terms of patent volume over the 10-year period and for patents published in heated tobacco and nicotine vapour technologies. For smokeless tobacco technologies, the United States exceeds China.
- For the top companies by patent volume, China is the most focused region, led by CNTC and PMI. Japan is the most focused country by Japan Tobacco and BAT. Kimree Technology, Nerudia (owned by Imperial Brands), and Nicoventures (owned by BAT) have mainly focused on publishing their patents through the World Intellectual Property Organization.

2 Summary

This report presents an overview of the patent landscape for tobacco harm-reduction technologies based on analysis of patent publication data from the past 10 years of activity. Three technology spaces were investigated: heated tobacco technologies, nicotine vapour technologies, and smokeless tobacco technologies. The results of this analysis give several insights including which companies are most active in patenting their tobacco harm-reduction technologies, which geographic regions these companies value for patent protection, and overall trends in research and development (R&D) in each technology space.

The first key insight is that tobacco companies such as Philip Morris International (PMI), British American Tobacco (BAT), and China National Tobacco Corporation (CNTC) maintain the largest patent portfolios in the space and therefore have a large degree of control over the technology used in the sector.

Another key theme is the trend of tobacco and nicotine technologies being patented under therapeutic classifications, meaning technologies that are concerned with the treatment of health issues instead of being solely focused on recreational use. This phenomenon has been identified before in the field of medical ethics and is known as the "pharmaceuticalization" of tobacco¹. This trend may indicate that tobacco companies are orienting their products toward more therapeutically focused areas. In this way, companies can penetrate new markets beyond traditional recreational use.

When analysing patents filed under these therapeutic classifications, some interesting trends can be observed. For example, tobacco companies appear to be investigating and patenting the use of nicotine to treat various disorders such as Alzheimer's and other neurological diseases. This finding further underlines the intention to shift to more therapeutic applications of these products.

Of particular note are those patents by PMI that involve the inclusion of biological sensors in their nicotine vapour technology lines. These patents outline devices that monitor and report on several indicators related to the user. Should these patents make their way into a tobacco companies' technology, we would likely see a shift in their overall purpose, again from simply recreational technology to devices that serve a measurable therapeutic purpose. In turn, this could result in tobacco companies' becoming potential partners with insurance companies, public health bodies, and other related industries and hence lead to further normalising these allegedly reduced-risk nicotine technologies. This could also result in greater access to the reduced-risk nicotine products.

That being said, how to integrate the needs of developing countries should be further explored. Many parts of the developing world appear to be left out from patent protection, suggesting not only a lack of local R&D capacities, but also a lack of interest by industry to disseminate potentially less harmful products to the developing world.

¹ Hendlin YH, Elias J, Ling PM. The pharmaceuticalization of the tobacco industry. Ann Intern Med. 2017;167(4):278-280. doi: 10.7326/M17-0759. https://pubmed.ncbi.nlm.nih.gov/28715843/

The pharmaceuticalization of tobacco also opens up the possibility for new uses of the technology through external collaborations. The patent activity indicates that there is interest in using the same technology that powers reduced-risk nicotine technology for other forms of drug delivery.

From the geographic analysis performed in each technology space, we can see that most of the patent activity is focused on countries that are considered "advanced" or "newly industrialised" according to the International Monetary Fund (IMF) classifications². China and the United States have the largest number of patents by far. Although there is some patent protection in "developing" countries, the numbers of patents applied to these countries are a fraction of those in developed countries. The implication is that few patents and inventions are being created in these countries, or that companies may not see value in protecting their technology in these countries.

Regarding the type of patents, many of the patents held by tobacco companies focus on improving their technology offerings, and there is little research being done on developing new core technologies.

The fact that patent protection remains primarily focused on wealthy nations is of concern from the perspectives of both public health and international development. It also offers a true assessment of how market participants evaluate the effectiveness of the patent system in many developing or least-developed countries.

To counter such evident gaps in technology protection, several steps may be considered. First, one may want to explore options to motivate tobacco companies to also offer access to potentially less harmful versions of tobacco products in low-income countries. Perhaps some corporate social responsibility index could be of help here. Second, one may want to explore ways of transferring technology to low-income countries. For this effort, one would need to understand in the first instance which patents could be transferred. Obviously, in areas where there is not even patent protection, there is no need to explore technology transfer because patented technology could be used there free of charge. We suspect, however, that other development issues may prevent the technology take-off. A feasibility study could be conducted, or existing best practices could be compiled that would help understand how technology transfer can be assured. In short, because wealth gaps lead to health gaps, preventing this should be a primary focus of any potential next steps.

² International Monetary Fund. World economic outlook update, January 2021. Accessed May 19, 2021. <u>https://www.imf.org/en/Publications/WEO/weo-database/2020/October</u>

A process for evaluating which strategy to use could involve a more in-depth patent analysis, which would take into account who owns key technology and for how long. This information can be used to provide recommendations to technology owners to transfer technology in a manner that makes sense for the country in question.

Hence, an analysis based on a further patent index would have to be unique for each country to assess how best to transfer technology. A good starting point would be to harmonise data on countries with tobacco harm-reduction patents and compile an index as an easily accessible database to facilitate this type of strategy.

Of course, tobacco-related public health issues are not confined to low-income countries, and therefore any strategy looking to release patent-protected technologies into a country will have to be performed on a countryby-country basis, taking into account the country's income level, pre-existing patent protections in place, and any unique cultural factors that could hinder the uptake of specific tobacco harm-reduction technologies.

This report offers a first look at the topic and, we hope, will serve as a baseline for a wider discussion and for further research into this area. Some new issues may emerge because patents can be seen as a reflection of innovation and a shift to tobacco health-related research. How will innovations with health and safety benefits be shared with low- and middle-income countries? The World Health Organization's Framework Convention on Tobacco Control makes little to no reference regarding patents or technology—even though harm reduction is part of the definition of tobacco control.

The manner by which intellectual property can be addressed in this debate is certainly an area that deserves more attention.

3 Introduction

Allegedly reduced-risk nicotine technologies refer to products that are designed to deliver nicotine using methods other than combustion. These products include e-cigarettes, heated tobacco products, and oral tobacco, and are generally considered less harmful for the user and for bystanders than traditional tobacco products³. Although these technologies have the potential to improve public health with respect to the effects of smoking, they are largely neglected by the World Health Organization's Framework Convention on Tobacco Control (WHO-FCTC).

This report analyses the patent landscape of less harmful or reduced-risk recreational nicotine technology. To do so, we categorised tobacco harm-reduction technologies into three broad areas: heated tobacco technologies, nicotine vapour technologies, and smokeless tobacco technologies. These groups are used to form an opinion on the patent position in each of these technology spaces and to identify room for new technology developments in the tobacco harm-reduction space. The goal of this analysis is to enhance transparency surrounding patent activity in the tobacco harm-reduction space and find actionable insights on how this information may be used to promote further technology developments in this area. Strategies for reducing tobacco use fall outside the scope of this report; instead, this report focuses on analysing patent data in the recreational nicotine technology space.

³ US Food & Drug Administration. Products, ingredients & components. Updated May 28, 2020. Accessed May 19, 2021. <u>https://www.fda.gov/tobacco-products/products-guidance-regulations/products-ingredients-components</u>

4 Working Definition

Tobacco harm reduction is a public health strategy aimed at lowering the health risks of tobacco consumption. Tobacco harm-reduction technologies seek to provide methods for nicotine delivery that eliminate the need for tobacco combustion. Most commonly, public health strategies aim to decrease or eliminate cigarette use, design therapies to get people to quit smoking, and encourage people to switch to an allegedly safer nicotine technology. This report will focus on allegedly less harmful nicotine technologies.

This report draws upon the nicotine technology definitions used by the US Food and Drug Administration (FDA). According to the FDA, recreational nicotine products can be split into two broad areas⁴: smokeless tobacco products and electronic nicotine delivery systems (ENDS).

The common theme between these technologies is that nicotine is extracted from the precursor through methods other than combustion. For smokeless tobacco products, this is usually done through sucking (snus), chewing (chewing tobacco, plugs, twist), or other similar means.

For ENDS systems, extraction involves heating the nicotine precursor at a temperature low enough to prevent combustion, but high enough to produce a nicotine vapour that is inhaled by the user. Non-combustible technologies consist of two product spaces: ENDS, mainly nicotine vapour products (or e-cigarettes), and heated tobacco products. These products are similar in their mechanism of nicotine consumption; that is, there is no combustion involved, but they differ in their underlying technologies. Nicotine vapour products use a liquid nicotine mixture (e-liquid) as the nicotine precursor, while heated tobacco products use tobacco sticks that are heated in a device. This difference means that each product space has different design requirements. A more in-depth summary of these areas can be found in Table 1.

Product Space	Technology Areas	Application
Non-combustible	Inhaling appliances Construction details (including cartridges and battery parts) Shape/Structure and nature of electric heating Temperature control	Nicotine vapour product Heated tobacco products
Smokeless Oral Nicotine Products	Mixture of active ingredients	Pouches Chewing

Table 1: Tobacco harm-reduction product technology spaces

⁴ US Food & Drug Administration. Products, ingredients & components. Updated May 28, 2020. Accessed May 19, 2021. <u>https://www.fda.gov/tobacco-products/products-guidance-regulations/products-ingredients-components</u>

Methodologically, this review of patent data relied on technical assessment by a subject matter expert who reviewed relevant patent publications following the categorisation explained in Table 1 above. This research is considered a first exploration of the topic and was completed in a relatively short period of time and small budget. It has not been peer reviewed and should be read as a starting point for further in-depth analysis on the topic. This approach may imply a certain research bias because the analysis is based on the subject matter expert's judgment of patent publications. This bias may apply, for example, but not exclusively, to the analysis pertaining to the specific technology trends identified in this report. It is, however, common industry practice to use subject matter experts, and any potential imperfections arising from human judgment are commonly accepted. It is also commonly accepted that different subject matter experts would have different opinions and/or come to different conclusions as to the peculiar patent situation. For example, in patent disputes, it is fairly common that different subject matter experts come to different conclusions on the numbers and features of patents within a given technology space. Patent data has been sourced from the European Patent Office (EPO) and the World Intellectual Property Organization (WIPO). We consider the technical expert well qualified because he holds a Ph.D. in chemical engineering from Imperial College London. It is also worth mentioning that some of the analysis is based on proprietary patent analysis methods developed by OxFirst and sources and methodological approaches can therefore not be further disclosed. Among the further limitations, the patent data currently available are not very exact. Different sources can reflect different numbers of patents; this can be explained, for example, by errors such as, but not exclusively, typographical mistakes that can occur during the patent application process, as well as other issues. Counting patents can be difficult in developing countries that lack adequate patent statistics or toolkits to collect such data. The insights prepared in this report should be read in light of these limitations, as well as the limitations discussed in the disclaimer at the end of the text. We cannot offer any warranty as to the accuracy of the data.

For the purposes of this report, the three patent spaces analysed are heated tobacco technology, nicotine vapour technology, and smokeless (or oral) tobacco technology. These three technology spaces were chosen because of the fundamental differences in the technology on which they are based.

When gathering patent data, we omitted several fields that would normally skew the results, for example the popular use of nicotine as an insecticide and flavourings for nicotine technology. These patents were generally present in large numbers and do not provide valuable information to the tobacco harm-reduction technology space. Patents addressing combustible tobacco were also excluded from analysis using a custom query function.

When assessing corporate patent holdings, we found that the frequent use of subsidiary companies wholly owned by larger players often masks the true nature of the corporate landscape. For example, Nicoventures is owned by British American Tobacco and Nerudia by Imperial Brands. For the purposes of this report, however, companies are left separate unless the business structure is obvious from the outset. A brief description of the companies referenced in this report is shown below⁵.

- China National Tobacco Corporation (CNTC) is a state-owned Chinese company and the biggest cigarette corporation in the world.
- Philip Morris International Inc. (PMI) is a multinational cigarette and tobacco manufacturing company that sells products in more than 180 countries.
- British American Tobacco (BAT) is a British multinational company that manufactures and sells cigarettes, tobacco, and other nicotine products; it is a key competitor of PMI.
- Kimree Technology is a China-based private company that designs, produces, and distributes electronic cigarettes. The company sells products online⁶.
- Nerudia, owned by Imperial Brands, develops and manufactures nicotine products. The company mainly produces nicotine-infused liquids for use in vapour and e-cigarette products⁷.
- Nicoventures, owned by BAT, develops and manufactures nicotine products⁸.
- Japan Tobacco is a global cigarette manufacturing company that operates in more than 70 countries.
- Altria is an American corporation, operating in the United States, that produces tobacco, cigarettes, and related products.

⁵ Foundation for a Smoke-Free World. 2020 Index Ranking Report. Tobacco Transformation Index. September 2020. Accessed May 19, 2021. https://tobaccotransformationindex.org/docs/2020-Index-Ranking.pdf.

⁶ Bloomberg.com. Kimree Inc company profile and news. Accessed May 19, 2021. <u>https://www.bloomberg.com/profile/company/KREE:US</u>

⁷ Bloomberg.com. Nerudia Ltd company profile and news. Accessed May 19, 2021

⁸ Bloomberg.com. Nicoventures Trading Ltd company profile and news. Accessed May 19, 2021. <u>https://www.bloomberg.com/profile/company/0125613D:LN</u>

5 General Observations on the Patent Landscape

A patent search was performed using global patent data for the product spaces and related technology areas discussed for nicotine vapour technologies, heated tobacco technologies, and smokeless tobacco technologies. An estimated 73,758 patents were published between 2010 and 2020. The average annual growth rate in the number of patents published was about 4.7%.

These trends are shown in Figure 1.

Figure 1: Estimates of patents published in the three tobacco harm-reduction technology spaces worldwide between 2010 and 2020

10 yr patent publications in the tobacco harm reduction space

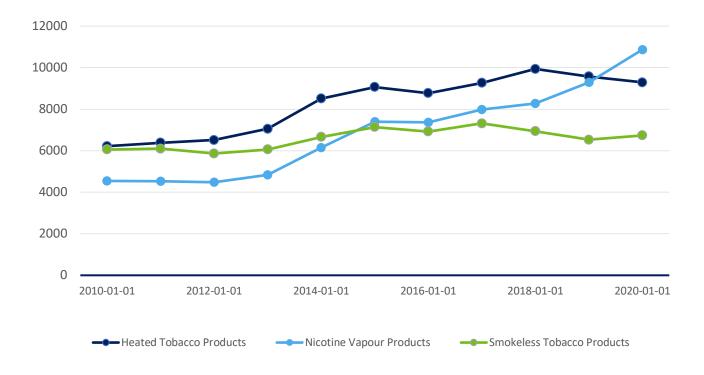


Table 2: Estimates of tobacco harm-reduction technology patent volumes, 2010-2020

Technology Area	Patent Number	% of Total	CAGR %
Nicotine Vapour Technology	26,540	36%	9.1
Heated Tobacco Technology	30,432	41%	4.1
Smokeless Tobacco Technology	16,786	23%	1.1

CAGR, compound annual growth rate.

Much of this growth over the past 10 years is due to developments in ENDS systems. The number of patents published in nicotine vapour technology grew at a rate of 9.1% per year, and for heated tobacco technology at a rate of 4.1% per year (Table 2). For comparison, the average annual growth rate of patent applications worldwide between 2009-2019 was 5.7%.

Nicotine vapour technology is the fastest growing field, and as of 2020 it has overtaken heated tobacco technology in terms of the number of patent publications observed in a single year. Historically, heated tobacco technologies have had the highest number of patents published each year, but patent publications have been slowing, and from 2018 they appear to be dropping. The growth in nicotine vapour technology patents has been steady since 2015, and if this trend continues, the technology space will overtake heated tobacco technology for having the largest number of patents.

Both ENDS technology spaces saw a large volume of growth starting in 2013, and this is likely due to a consolidation of ENDS-related technologies^{9 10 11 12 13 14}. This fast growth in a largely unregulated market created an extremely fragmented technology landscape, with much of the development being done by a large number of start-ups looking to capture the growing market. A number of international tobacco companies acquired existing companies operating in the ENDS space. This likely catalysed the growth rates seen in the heated tobacco technology and nicotine vapour technology spaces. Of the two spaces, heated tobacco technology initially had more patent activity, possibly because this type of technology has been of interest to tobacco companies for a longer period of time. However, recent trends show that technology progress has slowed in this area, and patent activity is giving way to innovations in the nicotine vapour technology space.

Smokeless (oral) tobacco technology has experienced the slowest growth rate. A major reason for this is that smokeless tobacco products tend to be extremely simple, designed to be chewed, sucked, or used via nicotine pouches. In contrast, ENDS systems comprise several specially designed mechanical and electrical components, each of which can be patented. Therefore, in comparison, the number of patents for smokeless technologies is always bound to be lower relative to nicotine vapour and heated tobacco products.

⁹ Rom O, Pecorelli A, Valacchi G, Reznick AZ. Are E-cigarettes a safe and good alternative to cigarette smoking? Ann N Y Acad Sci. 2015;1340:65-74. doi: 10.1111/nyas.12609.https://pubmed.ncbi.nlm.nih.gov/25557889/

¹⁰ Orellana-Barrios MA, Payne D, Mulkey Z, Nugent K. Electronic cigarettes-a narrative review for clinicians. Am J Med. 2015;128(7):674-681. doi: 10.1016/j.amjmed.2015.01.033.

¹¹ Gustafsson K. Imperial tobacco agrees to acquire Dragonite's e-cigarette unit. September 2, 2013. Accessed May 19, 2021. https://www.bloomberg.com/news/articles/2013-09-02/imperial-tobacco-agrees-to-acquire-dragonite-s-e-cigarette-unit

¹² Arcieri K. Lorillard acquires British e-cig maker for \$48.6M. October 1, 2013. Triad Business Journal. Accessed May 19, 2021. https://www.bizjournals.com/triad/blog/2013/10/lorillard-acquires-british-e-cig.html

¹³ Business Wire. Altria completes acquisition of Green Smoke. April 1, 2014. Accessed May 19, 2021. <u>https://www.businesswire.com/news/home/20140401006617/en/Altria-Completes-Acquisition-of-Green-Smoke</u>

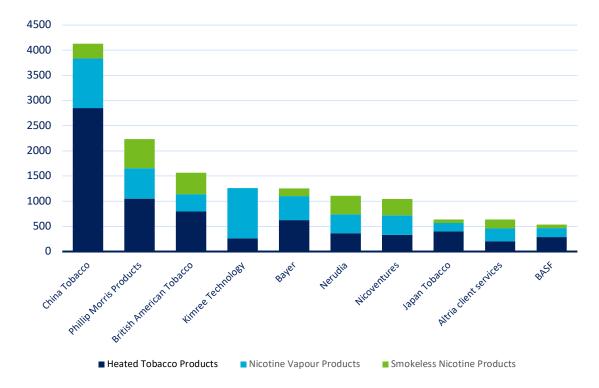
¹⁴ Spanier G. Philip Morris buys e-cigarette maker Nicocigs as it warns of falling profits. June 26, 2014. The Independent. https://www.independent.co.uk/news/business/news/philip-morris-buys-e-cigarette-maker-nicocigs-it-warns-falling-profits-9565087.html

This analysis shows trends in the overall tobacco harm-reduction space but evaluating the activities of each individual company also gives insights into the overall trends of the industry. Figure 2 shows the ownership distribution of patents held by the top 10 companies by patent publication. CNTC has the largest number of patents across the three technology spaces.

Geographic patent activity is discussed in greater depth later in the report. However, it should be noted that companies operating in East Asia appear to be more focused in their patent activity, filing a majority of their patents in a single area, with a smaller number in other tobacco harm-reduction areas. Examples of this are as follows:

- CNTC, a state-owned manufacturer of tobacco products, published 69% of their patents in heated tobacco technologies, with the majority of these related to specific processing and preparation methods for tobacco to be used in heated tobacco devices, with a smaller focus on the devices themselves.
- Kimree Technology, a privately owned, technology-driven manufacturer and distributor of e-cigarette devices based in China, focused 79% of their patent portfolio on core e-cigarette technologies.
- Japan Tobacco, an international cigarette manufacturing company, published 63% of their patent portfolio in heated tobacco technologies.

Figure 2: Estimated patent distribution for the top 10 companies by number of patents filed between 2010 and 2020



Patents in each technology space by top 10 companies by number of patents

For the other companies shown in Figure 2, their patent publication activities were more evenly distributed among the three technology spaces. Of note, Bayer has a large number of patent publications in heated tobacco technology. These patents refer to technologies surrounding the growing, harvesting, and processing of tobacco, along with the manufacture and use of nicotine (many patents referred to the use of nicotine as an insecticide, which were omitted from our analysis).

Kimree Technology is exclusively working on non-combustible systems, and while its patent portfolio is mainly focused on nicotine vapour technology, there is also a small number of patents in the heated tobacco technology space, showing that there is some technology crossover in these areas (Table 3).

US and European headquartered tobacco companies appear to have dedicated at least some of their research toward smokeless tobacco technology; however, this trend is not seen in the larger companies located in Asia. Newer "innovation" companies such as Nicoventures and Neruda (owned by BAT and Imperial Brands, respectively), which are set up by larger tobacco companies as research hubs, have a more evenly distributed patent portfolio. These companies have a roughly even split in all three technology spaces, whereas the older, more established tobacco companies remain focused primarily on the heated tobacco technology space (Table 3). Note that patent activity associated with combustible tobacco is excluded from this analysis.

	Patents Top Publication Top Technology					
Company	Total	Heated Tobacco	Nicotine Vapour	Smokeless Tobacco	Country	Area
China National Tobacco	4,129	69%	24%	7%	China	Heated Tobacco Technologies
Philip Morris International	2,234	47%	27%	26%	China	Heated Tobacco Technologies
British American Tobacco	1,564	51%	22%	27%	Japan	Heated Tobacco Technologies
Kimree Technology	1,260	21%	79%	0%	WIPO	Nicotine Vapour Technologies
Nerudia	1,105	33%	34%	33%	WIPO	Nicotine Vapour Technologies
Nicoventures	1,042	32%	37%	31%	WIPO	Nicotine Vapour Technologies
Japan Tobacco	636	63%	26%	11%	Japan	Heated Tobacco Technologies
Altria Client Services	635	32%	40%	28%	USA	Nicotine Vapour Technologies

Table 3: Estimated top 8 tobacco companies by patent publications, with top publication country and toptechnology area between 2010 and 2020

Nicoventures is owned by British American Tobacco; Nerudia is owned by Imperial Brands.

6 Geographic Patent Activity

As mentioned previously, geography appears to be a factor when analysing patent activity in the tobacco harmreduction space. An analysis of the geographic distribution of patent activity offers several insights.

The first observation is that, outside of China, patent activity is most prevalent in countries that are considered advanced or developed using the International Monetary Fund (IMF) classifications¹⁵. Table 4 shows the total number of patents published in the top 10 countries. The data indicate that China and the United States have the highest focus for patent activity, which then drops off for the other countries.

Total	Heated Tobacco Technology	Nicotine Vapour Technology	Smokeless Tobacco/Nicotine Technology	Total
China	49%	34%	17%	46,850
USA	34%	37%	29%	42,189
WIPO	36%	35%	29%	24,936
Japan	35%	33%	32%	17,620
Australia	37%	30%	33%	10,764
Republic of Korea	37%	33%	30%	10,171
EPO	36%	36%	27%	9,551
Canada	36%	32%	31%	8,689
Russia	43%	33%	24%	2,319
Taiwan	33%	28%	39%	2,240
Average	38%	33%	29%	-

Table 4: Estimated distribution of tobacco harm-reduction patent publications between 2010 and 2020)

In Asia, the patent activity is dominated by China, which has the highest number of patent publications in all areas. There is some publication activity in other Asian countries or regions, particularly in Japan, Republic of Korea, and Taiwan. Very little patent activity is registered in India, Philippines, Malaysia, or Vietnam.

¹⁵ International Monetary Fund. World economic outlook update, January 2021. Accessed May 19, 2021. <u>https://www.imf.org/en/Publications/WEO/weo-database/2020/October</u>

In North America, patent activity is dominated by the United States, with some activity registered in Canada. Mexico is negligible in terms of patent publications compared to Canada and the United States; only 1,471 patents were published in the past 10 years of patent activity in Mexico. South America has a small amount of patent activity, with Brazil being the focus of patent activity in this region.

In the region of Africa and the Middle East, there is no registered patent activity outside of Israel, Morocco, and South Africa.

Patent activity in each technology space varies among countries, which may be an indicator of individual country policy or simply the popularity of technology spaces in these countries. For heated tobacco technology, China and Russia have a higher than average number of patent publications, outperforming other countries by 11% and 5%, respectively. Patent publications in the United States and Europe (mainly reflected in European Patent Office registrations) have the highest percentage for nicotine vapour technology, with their portfolios exceeding the average by 4% and 3%, respectively. Taiwan has the highest focus on smokeless tobacco technology, with 39% of the nation's patent portfolio relating to these technologies, 10% higher than the average. This is an area where China appears to underperform, as only 17% of patents registered in China include publications in the smokeless tobacco technology space, compared to the 29% average across other countries.

7 Technology Trends

A. Heated Tobacco Technology

The heated tobacco technology sector is dominated by companies operating in the tobacco and cannabis space, with the top three companies—CNTC, PMI, and BAT—accounting for approximately 15% of patents published in the past 10 years.

Geographic Analysis

Figure 3 illustrates the patent activity in this area by geographic region. Most patent publications for heated tobacco are concentrated in high-income or upper-middle-income countries, in particular China (estimated 22,956 publications) and the United States (estimated 14,344 publications).

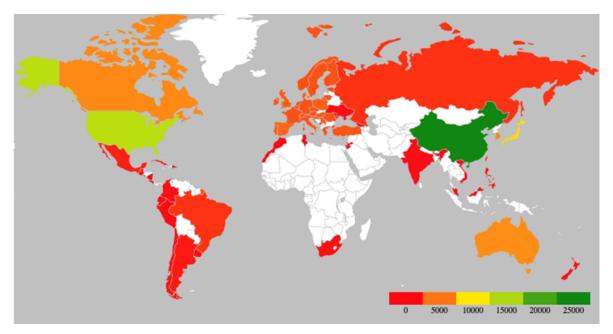
In Asia, the patent activity is dominated by China, which has the highest number of patent publications in the heated tobacco technology space, although there is some publication activity elsewhere, particularly in Japan, Taiwan, and the Republic of Korea. There is a small amount of patent activity in India, Philippines, Malaysia, and Vietnam.

In North America, patent activity is dominated by the United States, with some activity registered in Canada. Mexico lags behind in terms of patent publications compared to Canada and the United States; only 1,471 patents were published during the past 10 years of patent activity in Mexico.

South America has a small amount of patent activity, with Brazil being the main focus of patent activity in this region, where 2,191 patents are registered. There is a smaller amount of patent activity in the surrounding countries, namely Argentina (998 patents) and Chile (556 patents). Other countries in this region with registered patent activity appear to have less focus and generally register only about 100 to 300 patents.

The Africa and the Middle East region, outside of Israel, Morocco, and South Africa, had no registered activity.

Figure 3: Geographic heat map of estimated numbers of patents published between 2010 and 2020 in the heated tobacco technology space (white indicates no patent activity)

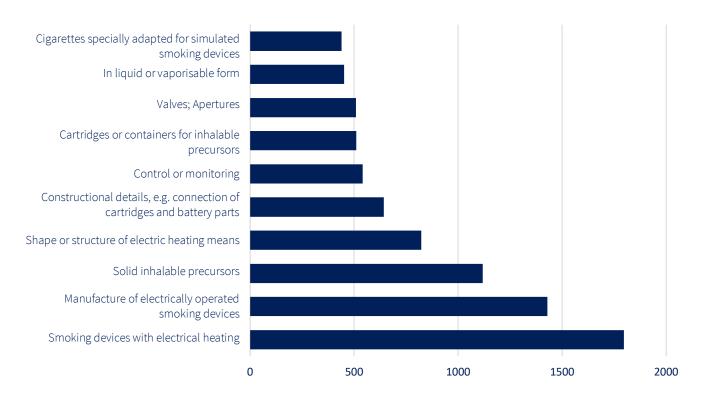


Technology Analysis

About 45% of patents published in the heated tobacco space are filed under tobacco classifications, and Figure 4 lists the topics these patents address. Most patents in this technology space relate to the design and manufacture of heated tobacco devices. A particular focus appears to be on the heating element, which companies aim to improve to increase the efficiency of their technology.

Other focus areas are the shape and nature of the mouthpiece and inhaling appliance, construction details, valves used in the device, and the software that controls them. The treatment of tobacco to make it more suitable for use in heated tobacco devices, as well as design aspects relating to its use (such as in a cartridge, rod, or capsule), are also of high importance. Although the former concern is related to health and efficiency, the latter is likely tactical and related to individual brand identity and an attempt to create a "vendor lock-in" by ensuring that a specific manufactured technology can only work with certain types and geometries of tobacco precursors.

Figure 4: Estimated technology trends for heated tobacco technology patents published under tobacco classifications



Top technology topics for patents published under tobacco classifications in the heated tobacco technology space

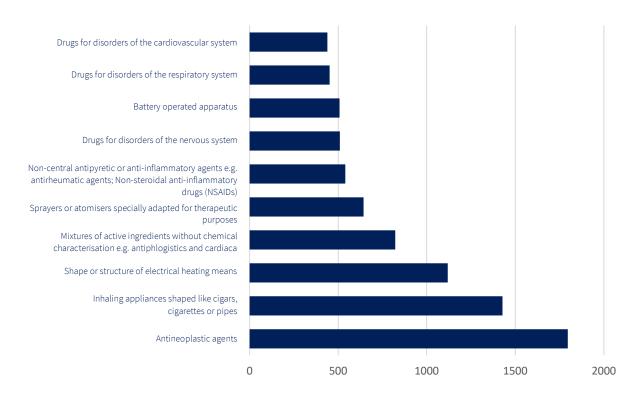
About 38% of patents are filed under therapy-related codes, as analysed in Figure 5. Most of the patents filed in this field deal with the supposedly therapeutic use of tobacco technology, including, but not limited to, nootropic applications of nicotine and vaping technologies for medicinal uses such as drug delivery. Many of these patents simply refer to medical terminology that can be applied to heated tobacco devices, such as inhalers and battery-operated devices, for which it is easy to see the relation. This is in line with the observation by Hendlin et al that tobacco companies are seeking to make their devices more medically focused¹⁶.

There are, however, some interesting observations. Antineoplastic agents are mentioned frequently and refer to medications used to treat or prevent cancer. This could indicate that companies are researching antineoplastic agents as potential additions to tobacco technology to further reduce their cancer risk.

Epidemiological studies have shown that nicotine has potential therapeutic uses, particularly for neurological disorders such as Parkinson's disease. High patent activity in this area indicates a shift in R&D strategy to capitalise on this potential use.

¹⁶ Hendlin YH, Elias J, Ling PM. The pharmaceuticalization of the tobacco industry. Ann Intern Med. 2017;167(4):278-280. doi: 10.7326/M17-0759. https://pubmed.ncbi.nlm.nih.gov/28715843/

Figure 5: Estimated technology trends for heated tobacco technology patents published under therapeutic classifications



Top technology topics for patents published under tobacco classifications in the heated tobacco technology space

The remaining patents in this area relate to chemical developments. Chemicals are often used as additives in the final product. Specific chemical manufacturing processes, including fermentation or enzyme synthesis, are regularly applied. These are highly technical topics that do not relate specifically to tobacco harm reduction and will therefore not be researched further.

The company with the largest portfolio in heated tobacco technology is CNTC. Their portfolio encompasses the full range of technology spaces. Their technology focus during the past 10 years appears to include the following:

- CNTC has a large emphasis on the manufacture of tobacco used in heated tobacco products, particularly processes that use steaming or curing, which affect taste of the final product, efficiency of nicotine extraction, and chemical content.
- CNTC's focus appears to be on specific manufacturing details for the tobacco used in a heated tobacco device, with fewer patents dedicated to the devices themselves.
- Other patent areas include processes for altering tobacco, mainly through the use of organic solvents or adsorption processes, to remove chemicals that may have remained behind otherwise.

PMI is the second largest patent holder, and their patent focus appears to be on the construction of heated tobacco devices rather than the tobacco used in the devices.

- The company has filed a number of patents relating to liquid precursors under the heated tobacco technology space, which could indicate the company is interested in developing devices that are considered hybrids between nicotine vapour technology and heated tobacco devices.
- 90% of PMI's top patent categories relate to device design. This indicates that PMI may see most of the value proposition of heat-not-burn technology being on the device.
- Unlike CNTC, PMI appears to focus its R&D efforts on device-level inventions rather than tobacco production processes.
- Several patents by PMI reference using chemical heating rather than electrical heating in their devices, which may indicate a search for alternatives to electric heating in their products.

BAT's patent portfolio shows a similar trend to that of PMI and appears to be mixed between device-level inventions and inventions relating to additives.

- BAT has a high focus on filters, additives embedded in filters, and manufacturing processes allowing cigarettes to be used in heat-not-burn devices. This suggests that BAT has a high level of focus on the tobacco precursor used in the device.
- Similar to PMI, BAT appears to be focusing on device-specific inventions including device design, the nature of the heating element, and related processes.

It is interesting to note that some of these observations for patents filed by companies are consistent with past research looking at how companies allocate their capital in the tobacco space¹⁷.

B. Nicotine Vapour Technology

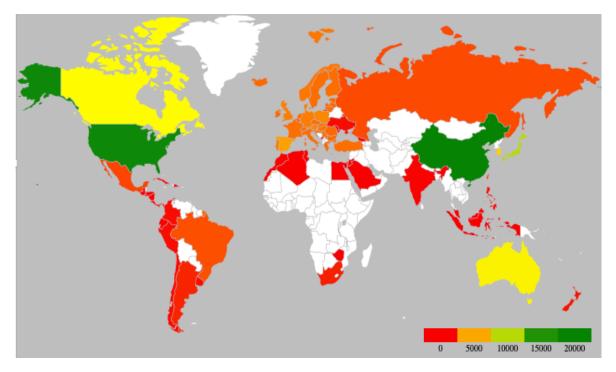
Like heated tobacco technology, the nicotine vapour technology space appears to be dominated by companies operating in the tobacco and cannabis sectors. Kimree Hi-Tech, CNTC, and PMI seem to hold about 10% of all patents granted during the past 10 years.

Geographic Analysis

A geographic representation of patent activity is shown in Figure 6. Similar to patents for heated tobacco technologies, most patent publications for nicotine vapour technologies are, with the exception of China, concentrated in high-income countries. The highest-ranking countries are China (15,929 publications) and the United States (15,610 publications).

¹⁷ Foundation for a Smoke-Free World. 2020 Index Ranking Report. Tobacco Transformation Index. September 2020. Accessed May 19, 2021. https://tobaccotransformationindex.org/docs/2020-Index-Ranking.pdf

Figure 6: Geographic heat map of estimated numbers of patents published between 2010 and 2020 in the nicotine vapour technology space (white indicates no patent activity)



In Asia, the patent activity seems similar to that for heated tobacco technologies, with China appearing to have the highest number of patent publications, followed by Japan, Taiwan, and Republic of Korea. In contrast, only small numbers of patents were registered in India, Philippines, Malaysia, or Vietnam.

In North America, patent activity also seems to follow the same trend as for heated tobacco technologies, with the United States being the dominant player, Canada following behind, and Mexico having the least patent activity. South America has the highest amount of patent activity in this sector, being focused on Brazil.

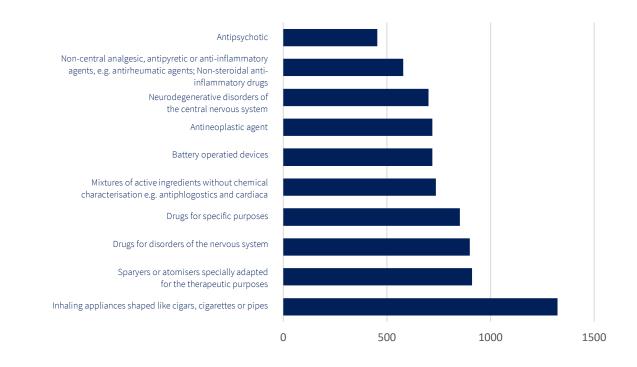
In the Middle East and Africa, patent activity seems limited to South Africa, Morocco, Egypt, and Saudi Arabia.

Technology Analysis

During the last 10 years, there has been significant publication activity related to therapeutic technologies, with 48% of patents being filed under classifications related to medical or veterinary science (A61 of the Cooperative Patent Classification). This may indicate a push toward therapeutic applications in areas related to nicotine vapour technology. An analysis of these topics is shown in Figure 7, which again illustrates similar trends as shown in Figure 5. The number of patents relating to vapour technologies for therapeutic purposes shows a shift in the field, with companies looking to use their vapour technology for more than just nicotine. Although currently much of this focuses on cannabinoids, which can be used in an e-cigarette in place of nicotine-containing e-liquid, there is some research into using other therapeutic drugs, such as melatonin.

Once again, there is mention of "drugs for disorders of the nervous system." This may suggest that companies in the vapour technology space may be looking to pivot their offerings to provide nicotine to treat neurological disorders.

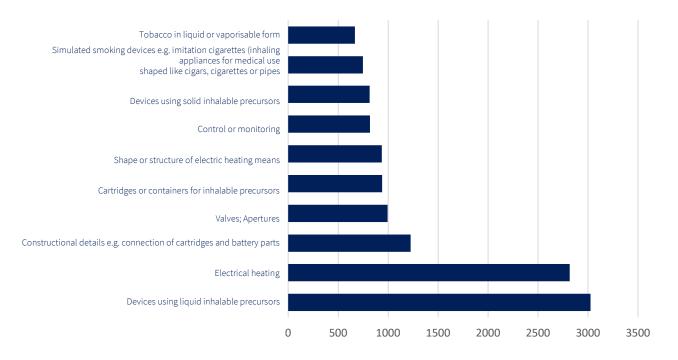
Figure 7: Estimated technology trends for nicotine vapour technology patents published under therapeutic classifications



Top technology topics for patents published under therapeutic classifications in the nicotine vapour technology space

An analysis of the most common tobacco topics can be found in Figure 8. Most of these patents are related to the device, specifically the overall device design and electrical heaters. There is a much smaller focus on the liquid precursor used, unlike what was seen for the heated tobacco technologies. This is likely due to the simplicity of e-liquid. It is also likely that most of these patents have been filtered out because they are only related to flavourings.

Figure 8: Estimated technology trends for nicotine vapour technology patents published under tobacco classifications



The company with the largest nicotine vapour technology portfolio is Kimree Technology, which is a designer, producer, and distributor of e-cigarette devices. Kimree Technology was also present in the heated tobacco technology space, showing some crossover among technology areas.

- Kimree Technology's patent portfolio focuses exclusively on the manufacture and design of devices such as e-cigarettes. Their largest classification category is tobacco, and all the patents in this category refer to either e-cigarette devices or their components.
- Their second largest category is electronics, which refers to electrical components used within the company's technology (wiring, circuitry, and other components).
- Some of the patents reference devices with built-in user interfaces (e.g., LED screens), which indicates that this may be a priority for Kimree Technology going forward.
- Many of the patents are for refillable e-liquid cartridges. Kimree Technology does not appear to manufacture its own e-liquid; therefore, it is logical for the company to enable users to fill cartridges compatible with their devices using their own nicotine sources.

CNTC is the second largest patent holder in the nicotine vapour technology space, and their patent focus is similar to that of Kimree Technology, mainly focusing on design features.

• CNTC seems to have a large research emphasis on heating technologies, which are used in nicotine vapour products to convert e-liquid into inhalable vapour; electrical heating technologies are their biggest patent filing by a large margin.

- There seems to be a relatively large patent volume on devices that do not require heating, indicating that CNTC may be looking into chemical heating methods or into precursors that more readily form a vapour without heat supplied by an electronic heating element.
- Overall, though, their patent portfolio appears to pertain mainly to components and specific construction details of nicotine vapour technology.

PMI is the third largest patent holder for nicotine vapour technologies and has the largest number of therapyrelated patents among the top three companies in the space. Similar to the other two companies, PMI appears to have registered most of its patents with reference to medical terminology such as inhalers.

- Many of PMI's patents in the therapeutic field also refer to cartridges and cartridge assemblies for generating aerosols, which could be applied to certain therapeutic applications, although most are still focused on nicotine.
- The most interesting insight, however, is that some of these patents appear to also refer to biological sensors, which are designed to monitor the characteristics of their users and provide therapeutic data.
- PMI may be planning on positioning their e-cigarette devices as therapeutic monitoring systems, or at the very least licencing this technology to companies that look to provide this service.
- A number of patents seem to relate to solid precursors and devices using multiple chemical sources, which further supports the hypothesis that the company may be pursuing heated tobacco/vapour hybrid devices.
- Other than this, the most popular technology trends for PMI appear to refer to components used in their ecigarette devices, such as valves, heating elements, and other components.

C. Smokeless Tobacco Technology

The smokeless tobacco technology field has the largest number of patents published in therapeutic applications, with 68% of publications being filed in this area. The remaining patents are related to the chemicals and tobacco used as the nicotine precursor in smokeless tobacco technology. There has been less development in these areas than in allegedly therapeutic applications, likely because the processes for producing nicotine and tobacco for such applications are well established.

Geographic Analysis

Figure 9 illustrates patent activity in this sector by geographic region. The overall trend for smokeless tobacco technologies appears similar to that of the other two patent spaces, although there seems to be a reversal between the United States and China. The United States is the highest ranked country with 12,234 patents published, and China is second with 7,964 patents published. The heat map should be viewed as a gradient rather than binary.

In Asia, patent activity for smokeless tobacco technology, while apparently led by China, is more proportional in relation to other countries in the region than was observed in the other technology spaces. Other servicedriven economies in Asia with significant patent activity include Japan (6,376 patents), the Republic of Korea (2,991 patents), Taiwan (872 patents), and India (400 patents). Although other developing economies located in East Asia such as Philippines, Indonesia, and Thailand have registered patent activity, the numbers of patents are a fraction of those seen in the previously mentioned economies.

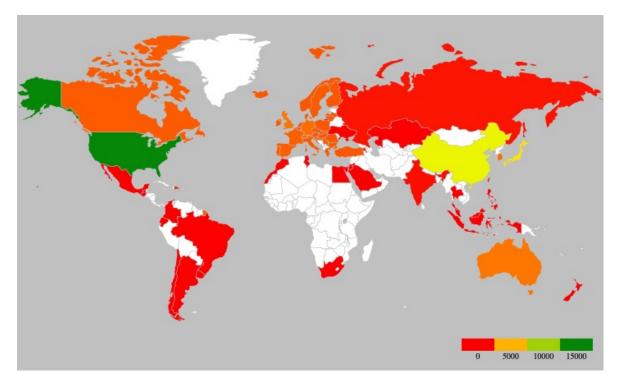
North America is again dominated by the United States, followed by Canada (2,523 patents) and finally by Mexico, where there were only six patents for smokeless tobacco technologies.

In Europe, most patents are published through the European Patent Office, which enables patent protection throughout its member countries.

South America follows the same trend that was seen in the previously discussed technology spaces, with Brazil being the country catching most of the attention. Other countries do not register significant patent activity, and, where present, patent numbers are in the single digits.

Similar to the analysis done on the other technology spaces, this analysis suggests no particular registered activity in the Africa and the Middle East regions outside of Israel, Morocco, South Africa, and Egypt.

Figure 9: Geographic heat map of estimated numbers of patents published between 2010 and 2020 in the smokeless tobacco technology space (white indicates no patent activity)¹⁸



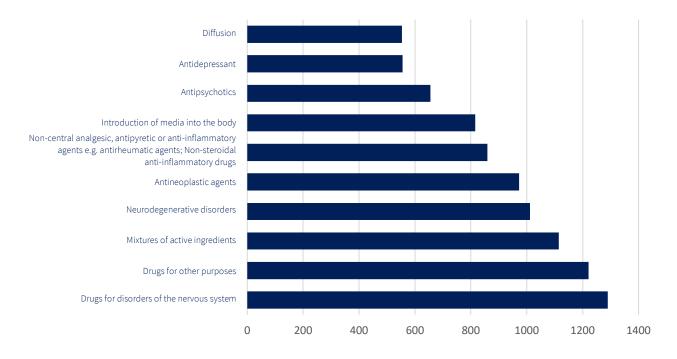
¹⁸ Espacenet – Patent Search. Accessed May 19, 2021. <u>https://worldwide.espacenet.com</u>

Technology Analysis

An analysis of the patents published in therapy-related fields is shown in Figure 10. Because there is a higher patent focus for therapeutic applications in this technology space, we see a further emphasis on the various uses for nicotine in medical applications, those mainly being treatment of neurological disorders such as Alzheimer's, therapeutic use of nicotine to eliminate smoking, and its effect as a nootropic. These themes are not unique to this technology space; however, they appear to be most prevalent here.

There is large patent activity relating to the mixtures of active ingredients within a technology. Patent activity here seems to encompass mixtures with low concentrations of toxic compounds, additives that can regulate the uptake of nicotine into the body, and compounds that are anticarcinogenic in nature. Other patents in this area seem to relate to compounds that decrease potential irritation caused by use of the products that fall under this space.

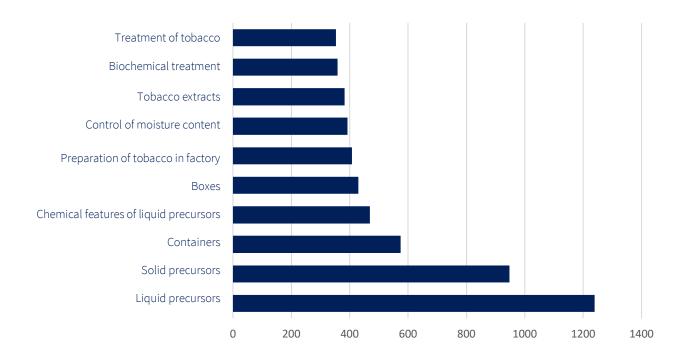
Figure 10: Estimated technology trends for smokeless tobacco technology patents published under therapeutic classifications



Top technology topics for patents published under therapeutic classifications in the smokeless tobacco technology space

An analysis of patents published under tobacco specific classifications is shown in Figure 11. There is a large research focus on liquid precursors for smokeless tobacco technology. This refers to liquid nicotine, which is then added to other components to create the technology. Because of its simplicity, the liquid precursor can be added to virtually anything and is likely a necessary component in the manufacturing of most synthetic nicotine technology. Closely behind are patents for solid precursors, which refer to the solid nicotine crystals commonly used in technology such as tobacco-free snus, whereby nicotine salts are added to a substrate such as tea leaves.

Figure 11: Estimated technology trends for smokeless tobacco technology patents published under tobacco classifications



Top technology topics for patents published under tobacco classifications in the smokeless tobacco technology space

PMI seems to be the largest patent holder in the smokeless tobacco technology space. Its patents in this area are relatively simple and refer to the nicotine sources used in the smokeless tobacco technology space, as well as the design of the technology as a whole.

- About 13% of PMI's patents seem to be in allegedly therapeutic areas and refer mostly to nicotine inhalers, which are traditionally a prescription technology for nicotine cessation.
- About 4% of their patents seem to refer to chemical development. Many of PMI's patents appear to refer to different physical forms of nicotine (e.g., solid, liquid, tobacco), with different forms being suitable for different types of products.
- PMI's research on inhalers appears focused on mechanical pump-operated inhalers similar to those used to treat asthma. These patents tend to outline devices that release nicotine as a powder or naturally occurring aerosol.
- It is unclear whether PMI may be aiming to release these products to the recreational market.
- Other than this, many of the patents relate to brand-specific applications such as containers and presentation of the product.

BAT appears to be another important patent holder in smokeless tobacco technology. In particular, BAT seems to have a large number of patents for oral tobacco, mainly snus or snus-like technology.

- Featured are patents ranging from the manufacture of snus pouches to the wrapper or "fleece" surrounding the pouches.
- About 12% of the patents seem to be for alleged therapeutic purposes, again mainly referencing medical inhalers for nicotine aerosols, which are designed mainly for nicotine cessation.
- Finally, about 5% of BAT's patents appear to refer to chemical development.

Nerudia, owned by Imperial Brands, appears to be the third largest patent holder in smokeless tobacco technology. Nerudia appears to have a higher focus on therapeutic applications than either PMI or BAT.

- 22% of the patents seem to be filed under therapeutic classifications, compared to approximately 13% filed by BAT and PMI individually.
- Nerudia does not appear to dedicate any of its patent publications to the development of new chemicals.
- The firm's patents appear to be less focused on nicotine inhalers, which are a large focus for PMI and BAT.
- The largest numbers of patents by Nerudia appear to relate to liquid nicotine precursors, mainly nicotine gels, which can be consumed orally or used as a precursor in other types of nicotine cessation therapies.

D. Activities of Pharmaceutical Companies in Smokeless Tobacco

Because this field is most closely related to pharmaceuticals, it can make sense to analyse the patent holdings of pharmaceutical companies with registered activity in the smokeless tobacco space. Of the patents published by pharmaceutical companies in the smokeless tobacco technology space, 72% seem to relate to therapeutic applications and focus almost entirely on nicotine cessation technologies; use of nicotine as a drug for treating neurodegenerative disorders, as discussed above; and drug-specific patents relating to dosages and treatment plans. Another 28% of patents appear to refer to chemicals, which suggests that chemical development is of importance to these companies; however, not much more of practical importance for tobacco harm-reduction policy can be determined. We may conclude that pharmaceutical companies' involvement in the smokeless tobacco technology space is related to medical treatment of addiction. There does not appear to be any indication that pharmaceutical companies are entering the recreational tobacco space. It should also be noted that the number of patents published is a fraction of that published by tobacco companies; however, this may be explained by the fact that nicotine cessation therapies make up a small fraction of these companies' product portfolios.

8 Conclusion

This report sought to analyse the patent activity of tobacco harm-reduction technology spaces over the past 10 years. Several insights may be gained.

From analysing the overall patent landscape, we confirmed that technologies allegedly reducing the harm caused by tobacco use are strongly protected by patents. There were approximately 73,758 patents published over the last 10 years, with an average growth rate of 4.7%. The fastest growing field seems to be nicotine vapour technology, which grew at a rate of 9.1% per year and, as of 2020, overtook heated tobacco technology for the largest number of patent publications per year. Currently, heated tobacco technology seems to have the highest number of patents. However, at current growth rates, nicotine vapour technology will likely overtake the sector by 2024 and may become the largest space in terms of patents published.

A geographic analysis shows that patent activity appears mainly focused on developed countries and China, while developing countries generally receive less attention.

Also worth noting is the increasing pharmaceuticalization of tobacco technology. This concept has been observed in the literature¹⁹; however, to the best of our knowledge this is the first time it has been substantiated with patent data. The results of this analysis suggest that tobacco companies are increasingly publishing their patents in therapeutic fields. This trend seems particularly relevant for ENDS patents.

One example of such innovations is biological sensors integrated within e-cigarette devices. Such developments can open the possibility for collaboration with the larger health care space and with companies developing or using similar technology. This collaboration could prove useful for normalising and gaining endorsement for allegedly safer nicotine technology.

This research suggests that pharmaceutical companies are not interested in entering the recreational nicotine space. Pharmaceutical companies seem to be focusing mainly on patenting their nicotine cessation technologies. There was some interesting patent activity related to therapeutic and medicinal uses of nicotine, which falls outside the scope of this report.

Several major questions remain unanswered. Although this report suggests that patents do not create a roadblock for introducing allegedly tobacco harm-reduction products to middle- and low-income countries, the lack of patent activity in these countries could be a result of companies seeing little value in protecting their technology in these regions. If tobacco companies are reluctant to enter these markets, it could result in marginalisation. The result would be a situation where the state of health may improve in developed countries²⁰ but continue to degrade in developing countries that do not have access to allegedly reduced-risk nicotine products. The lack of patents in these parts of the world can be seen in light of the gap in science and research

¹⁹ Hendlin YH, Elias J, Ling PM. The pharmaceuticalization of the tobacco industry. Ann Intern Med. 2017;167(4):278-280. doi: 10.7326/M17-0759. https://pubmed.ncbi.nlm.nih.gov/28715843/

²⁰ Provided these technologies achieve harm-reduction objectives.

between the global North and the South²¹. It also illustrates that many companies situated in developed countries are reluctant to file patents there. This can be explained by a host of different reasons: lack of trust in the local IP system, potentially dysfunctional IP bodies in some developing countries, potential lack of ability to enforce IP, or simply an assumption that the markets would be too insignificant to invest in IP there. The congruence of these phenomena suggests a widening gap between developed and developing countries. This is of concern, and future research should explore what practical measures can be taken to bridge the gap.

²¹ Kumar N, Janmohamed K, Jiang J, et al. An overview of tobacco control interventions in the Global South. Drugs Alcohol Today. 2020;20(3):207-218. Accessed April 29, 2021. <u>https://www.emerald.com/insight/content/doi/10.1108/DAT-03-2020-0013/full/html</u>

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