PatentVest

Continuous Glucose Monitoring (CGM): An Evolving Innovation Landscape.

December 2024

Contents

I. Summary

- Diabetes, particularly Type 2, is a prevalent chronic disease that disrupts the body's blood sugar regulation, affecting millions globally.

- Traditional monitoring methods, like finger-prick tests, provide limited snapshots of glucose levels, leaving a critical unmet need for ongoing data and personalized insights.

- Continuous Glucose Monitors (CGMs) have revolutionized diabetes management by providing real-time, continuous glucose readings, trends, and alerts, empowering individuals to make informed decisions about diet, exercise, and medication.

- This technology creates a massive market opportunity as the healthcare industry shifts towards preventative health and personalized medicine. Overall, the CGM market is projected to grow significantly, reaching a value of approximately $11.63 billion in 2024 and expanding to $21.32 billion by 2029

- Dexcom, a pioneer in glucose biosensing, has a rich history of product innovation in the CGM space, evolving from early models to their flagship G6 and G7 systems.

- Despite their pioneering role, Dexcom has recently faced financial headwinds, including a stock price decline (-31.53%, past year) and revised growth guidance, underscoring the need for a strategic shift.

- Stelo, Dexcom's first foray into the over the counter (OTC) market, is a strategically crucial product aimed at expanding the company's user base and countering competitors like Abbott's FreeStyle Libre.

- The CGM market is highly competitive, with key players like Abbott, Medtronic, and Roche vying for market share alongside Dexcom.
  - Abbott focuses on affordability and user-friendly designs, particularly with its FreeStyle Libre series.
  - Medtronic emphasizes integration with insulin pumps and predictive algorithms for advanced glucose management.
  - Roche, while a major player in diabetes care, has been less prominent in the CGM patent landscape compared to the other three companies.

- The CGM patent landscape is dynamic and increasingly active, with key players heavily investing in intellectual property to secure their innovations and market positions. In the last 5 years, there were over 5000 patent publications with a 10.90% CAGR.

  - Dexcom's aggressive filing strategy is the most striking trend, with a recent surge in patent filings indicating a focus on both breadth (patent families) and depth (total documents) to strengthen its IP position and potentially expand into new areas within CGM technology.

  - Abbott maintains a consistent patent filing trend, prioritizing quality over quantity, suggesting a focus on core technologies and key improvements.

- Medtronic and Roche have also been actively patenting in the CGM space, although their strategies differ in terms of focus and intensity.

- Key players like Dexcom, Abbott, Medtronic, and Roche prioritize key markets like the US and Europe, while also extending their reach to other regions.

- China and Japan also highlight the growing importance of these markets and the companies' desire to secure their position in these regions

- In the patent landscape of the Continuous Glucose Monitoring (CGM) market, understanding the complexities of patent litigation is crucial when comparing competing companies.

  - Dexcom vs. Abbott: The most prominent patent battles have been between Dexcom and Abbott. These two companies have been engaged in extensive patent disputes over their CGM technology.

- External factors, such as the rising popularity of GLP-1 drugs like Ozempic, could impact CGM demand, posing challenges and opportunities for all players in the market.

- Dexcom's ability to navigate these challenges and maintain its market leadership will depend on its ability to innovate, adapt, and strategically leverage its intellectual property.

To prepare this report we developed an exclusive IP landscape analysis for the Continuous Glucose Monitoring (CGM) space, unveiling the latest technological trends and identifying key players, including emerging startups pioneering innovative solutions. Our comprehensive analysis into patent activity, litigation trends, and competitive positioning, can empower stakeholders to navigate this dynamic market. To access this detailed analysis or to learn more about how our services can support your strategic goals, contact us today.

Let PatentVest be your partner in staying ahead of evolving technological landscapes.

***Request for Detailed Data**: For a more comprehensive analysis of the CGM market landscape, including detailed patent data, competitor profiles, and technology trends, please contact us to request access to the full report.*

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II. Market Landscape Overview

1. Dexcom's Stelo CGM: Features, Target Market, and Pricing Strategy

Features:

Dexcom's **Stelo** continuous glucose monitor (CGM) is a part of their OTC product line, leveraging much of the same technology as their flagship G6 model. The key features of Stelo include:

- **Non-invasive glucose monitoring** with real-time readings every five minutes.
- **Simplified user interface** designed for ease of use by non-professional users. Unlike prescription-based CGMs, Stelo does not require calibration.
- **Data tracking capabilities** via a mobile app, allowing users to monitor glucose trends over time.
- **Discreet form factor**, similar to other Dexcom CGMs, with the sensor worn on the upper arm.
- **Wear time of 15 days**, which provides longer use compared to some competitor products like Abbott's FreeStyle Libre.

These features are aimed at a broad consumer base, including those who do not require constant medical oversight but wish to track glucose trends.

Target Market:
Stelo is primarily targeted at two major consumer groups:

- **Type 2 diabetes patients not using insulin**: This group typically manages their condition through lifestyle modifications or oral medications rather than insulin therapy. Stelo allows these users to monitor glucose trends and better understand how their diet and activities impact their blood sugar levels without needing the precision required for insulin users.
- **Prediabetes and wellness-conscious individuals**: Individuals with prediabetes or those who want to track their glucose levels for general health and wellness purposes form another significant market. Stelo's user-friendly design and absence of a prescription requirement make it an attractive option for this group, similar to Abbott's Lingo.

Pricing Strategy:

According to Stelo Glucose Biosensor's official website, its pricing strategy is designed to cater to both one-time purchasers and subscribers, providing flexibility and cost savings. The base product, priced at $99 for a two-sensor kit covering up to 30 days, appeals to users seeking a non-recurring purchase. However, the subscription model offers a 10% discount, encouraging long-term commitment while allowing customers to cancel or pause as needed, providing both convenience and savings.
This pricing model reflects a strategic balance between accessibility and recurring revenue, ensuring affordability while fostering customer loyalty. Distribution is primarily through direct-to-consumer sales on the company's website, with additional savings through FSA/HSA eligibility, appealing to health-conscious, budget-savvy consumers. This approach effectively positions Stelo in a competitive market by offering flexibility and cost-saving incentives through its subscription service.

2. Significance of Stelo as Dexcom's First OTC CGM

The release of Stelo marks a significant milestone for Dexcom as it enters the over the counter (OTC) market for the first time. This move is important for several reasons:

Market Expansion:
Stelo allows Dexcom to expand beyond the prescription-based CGM market, which traditionally targets insulin-dependent diabetes patients. By entering the OTC market, Dexcom can reach a much larger audience, including people with prediabetes, Type 2 diabetes not using insulin, and even health-conscious individuals who may not have a clinical need for CGM but want to track their blood sugar levels. This opens up new revenue streams and enhances the company's market reach.

Regulatory Milestone:
Gaining **FDA approval for an OTC CGM** demonstrates Dexcom's ability to meet stringent regulatory requirements while simplifying its product for consumer use. OTC products require significant evidence of safety, ease of use, and low risk of misuse. By achieving this, Dexcom has positioned itself as a trusted provider of not just clinical, but also consumer-oriented health solutions.

Competitive Edge:
With the Stelo, Dexcom can compete more directly with **Abbott's FreeStyle Libre**, which has dominated the affordable CGM market for people managing their glucose without insulin. While Dexcom has typically been seen as a premium brand due to its advanced features and higher pricing, Stelo could allow the company to penetrate segments that Abbott has successfully captured through its more cost-conscious Libre series.

Consumer Health Focus:
As the healthcare industry trends toward **preventive health** and **wellness tracking**, having an OTC CGM enables Dexcom to tap into a growing consumer market interested in overall metabolic health, not just those managing diabetes. This positions Dexcom to potentially expand into wellness technology, competing not just with traditional CGM manufacturers but also health tech firms.

3. Key Competitors in the CGM Market

The primary competitors in the continuous glucose monitoring (CGM) market include Medtronic, Dexcom and Abbott, both of which recently launched over-the-counter (OTC) CGM systems.

- **Dexcom**: Dexcom's OTC CGM, Stelo, offers a highly accurate reading (with a Mean Absolute Relative Difference of around 9%) and a 15-day wear time, making it particularly popular among type 2 diabetes patients. Dexcom's reputation for high accuracy and real-time alerts remains one of its core strengths.
- **Abbott**: Abbott's Libre systems, such as the Libre Rio and Lingo, offer more affordability and simplicity, targeting non-insulin-dependent type 2 diabetes patients. Abbott's devices do not require calibrations and have broader use among prediabetic and wellness-conscious individuals.
- **Medtronic**: Medtronic offers the Guardian™ Connect CGM system, which is particularly integrated with its insulin pumps but can also be used independently for continuous glucose monitoring. Medtronic is targeting both type 1 and type 2 diabetes patients, emphasizing real-time data and insulin dosing

automation. Its CGM features smart algorithms that predict glucose levels ahead of time and provide proactive alerts up to 60 minutes in advance of a high or low glucose event, which is particularly valuable for insulin-dependent patients. However, Medtronic's systems generally require more frequent calibrations than Dexcom and Abbott, which has been a slight drawback for users.

Thus, Medtronic adds to the competitive mix by offering high-tech solutions with predictive algorithms and insulin pump integration, making it a strong player, especially among insulin-dependent diabetes patients. However, Dexcom and Abbott still dominate the OTC and non-insulin markets with their ease of use and lower calibration requirements.

4. Summary of the competitive landscape, highlighting market share, pricing strategies, and product features.

Diving deeper into the market outlook, below is presented some insights about the players previously mentioned.

1. Market Share

The global continuous glucose monitoring (CGM) market is highly competitive, with Dexcom, Abbott, and Medtronic leading the industry and commanding the majority of the market share. As of 2024:

- **Dexcom** commands approximately 40% of the CGM market globally, particularly leading in the U.S. with its G6, G7 models and now Stelo.
- **Abbott** holds a 36% market share, mainly due to the success of its FreeStyle Libre systems, which are widely adopted due to affordability and ease of use.
- **Medtronic** accounts for around 20%, primarily focusing on insulin-dependent patients using its Guardian Connect system, which integrates well with its insulin pumps.

Overall, the CGM market is projected to grow significantly, reaching a value of approximately $11.63 billion in 2024 and expanding to $21.32 billion by 2029.

2. Pricing Strategies

- **Dexcom**: The pricing strategy for the Stelo Glucose Biosensor is designed to cater to both one-time purchasers and subscribers, providing flexibility and cost savings. The base product, priced at $99 for a two-sensor kit covering up to 30 days, appeals to users seeking a non-recurring purchase. However, the subscription model offers a 10% discount, encouraging long-term commitment while allowing customers to cancel or pause as needed, providing both convenience and savings.

  This pricing model reflects a strategic balance between accessibility and recurring revenue, ensuring affordability while fostering customer loyalty. Distribution is primarily through direct-to-consumer sales on the company's website, with additional savings through FSA/HSA eligibility, appealing to health-conscious, budget-savvy consumers. This approach effectively positions Stelo in a competitive market by offering flexibility and cost-saving incentives through its subscription service.
- **Abbott**: Abbott's pricing strategy for the FreeStyle Libre product line emphasizes affordability and accessibility, leveraging partnerships with private insurers, Medicare, and veteran programs to minimize out-of-pocket costs. The retail price for uninsured users is around $65 per month for the FreeStyle Libre 2 sensors and $85 for the FreeStyle Libre 3 sensors. Insured users, depending on their coverage, may pay as little as $0 to $25 per month.

  Sales are conducted through retail pharmacies and online platforms, with additional discounts available through subscription models, ensuring consistent supply and cost savings for users. Abbott also offers

assistance programs for uninsured patients, reinforcing its commitment to accessibility. This multi-faceted approach supports a competitive position while fostering customer loyalty.

- **Medtronic**: The Guardian™ Connect Continuous Glucose Monitoring (CGM) system by Medtronic is designed for patients with Type 1 and Type 2 diabetes who manage their condition with multiple daily insulin injections. The pricing strategy is flexible, with options for insurance reimbursement, out-of-pocket payments, and potential financing plans. Sales are conducted through Medtronic's website, healthcare providers, and pharmacies, ensuring broad access to customers.
  While specific pricing is not listed on Medtronic's website, costs may vary based on insurance and location. Customers are encouraged to contact Medtronic or their healthcare provider for precise pricing details.

3. Product Features

- **Dexcom**: Dexcom Stelo glucose biosensor, which is designed for people aged 18 and older, offers a mean absolute relative difference (MARD) of 8.3%. This accuracy level is close to that of the Dexcom G7, which has a MARD of 8.2%. MARD is a key measure of CGM accuracy, representing the average percentage difference between CGM readings and reference blood glucose measurements. The Stelo provides up to 15 days of continuous wear, making it ideal for lifestyle tracking and monitoring glucose trends without the need for fingersticks or a prescription
- **Abbott**: Abbott's FreeStyle Libre 2 and 3 models provide glucose readings every minute but require users to manually scan the sensor to get real-time data. The Libre systems are more discreet and have a longer 14-day wear time, though they lack the real-time alerts that Dexcom offers. Their MARD is slightly higher at around 9.7%, but they remain accurate enough for most users.
- **Medtronic**: Medtronic's Guardian Connect system is geared towards patients requiring insulin therapy and provides predictive alerts up to 60 minutes in advance of glucose excursions. It has a higher frequency of calibration (typically twice per day) and offers integration with insulin pumps, which is a key differentiator for insulin-dependent patients.

Dexcom, Abbott, and Medtronic dominate the CGM market, each with distinct pricing and product strategies. Dexcom leads with high accuracy and advanced integration, Abbott excels in affordability and ease of use, while Medtronic's focus on insulin integration gives it a niche in the insulin-dependent diabetes market. As the CGM market continues to expand, pricing and technological advancements, particularly in ease of use and accuracy, will be key factors driving competitive differentiation.

III. Regulatory Strategy Analysis

1. Regulatory Pathway for Dexcom's Stelo OTC Approval

Dexcom followed a traditional but streamlined regulatory pathway for obtaining over-the-counter (OTC) approval for its Stelo product. This pathway closely resembles that used for its previous prescription-based products like the G6 but incorporated specific modifications to meet the requirements of an OTC product. The FDA's De Novo process was likely the basis for their regulatory submission, which is used for low- to moderate-risk devices without a predicate.

Key steps Dexcom took to secure FDA approval included:

- **Demonstration of Safety and Effectiveness**: Dexcom had to demonstrate that the Stelo system is as safe and effective as prescription-based continuous glucose monitors (CGMs) for its intended population. They used clinical trial data to prove the system's ability to provide accurate glucose readings without the need for medical oversight.

- **Simplified User Interface**: For an OTC designation, the FDA requires products to be user-friendly without healthcare provider intervention. Dexcom adjusted its software, ensuring that Stelo was straightforward to operate by consumers, particularly by reducing the complexity of alerts and removing medical treatment recommendations.

- **Risk Mitigation Strategies**: The product was submitted with risk management data showing that Stelo's use by non-professionals (i.e., patients) did not pose additional health risks. Unlike prescription models, Dexcom needed to prove that users could manage the product without calibration or healthcare guidance.

- **Post-Market Surveillance Plan**: A key part of FDA approval is establishing how Dexcom would monitor and mitigate any issues after Stelo is introduced to the market. This post-market data collection ensured continued compliance with FDA safety standards.

Ultimately, the FDA cleared Stelo as an OTC device because Dexcom's application convincingly demonstrated that the system met both the usability and safety standards for use outside of a clinical environment.

2. Comparison with Competitors' Regulatory Strategies

Abbott and Medtronic, Dexcom's main competitors in the CGM space, have followed similar regulatory pathways for their OTC products, but there are notable distinctions in how each company approached the approval process:

- **Abbott's Libre OTC Approach**: Abbott's strategy with its Libre series, particularly the Libre 2 and 3 OTC models, leveraged the FDA's 510(k) clearance pathway. This allowed Abbott to demonstrate that its product was substantially equivalent to a previously cleared device. The core difference in Abbott's approach was its emphasis on simplifying the user experience by eliminating real-time alarms and other clinical features that require medical oversight. Abbott managed to accelerate its approval process by focusing on a more affordable, streamlined product with a lower risk profile. Unlike Dexcom, Abbott's Libre systems are designed to give basic glucose trends without alarms, making the regulatory process slightly less complex.

- **Medtronic's Guardian OTC Pathway**: Medtronic's Guardian Connect followed a hybrid model of approval. While it retained advanced features like predictive alerts, which necessitated a lengthier approval process, Medtronic benefited from its existing FDA approvals for integrated CGM-insulin pump systems. By focusing on interoperability and predictive analytics, Medtronic had to submit more complex data to satisfy FDA requirements for real-time adjustments to insulin therapy. Medtronic's more intricate system required heavier clinical trial data, making its pathway longer and more challenging than Dexcom's.

Unique Advantages and Challenges for Dexcom

Advantages:

- **Streamlined Process for OTC Use**: Dexcom benefited from having previously secured FDA approval for prescription devices like the G6. By building on this data and focusing on simplifying the Stelo device, they shortened their regulatory timeline for the OTC version.

- **Higher Accuracy and Real-Time Alerts**: Unlike Abbott's Libre products, Dexcom was able to maintain some of its advanced features (e.g., real-time alerts) even in its OTC product, which gave Stelo a competitive edge in the market.

Challenges:

- **Increased Scrutiny for Real-Time Alerts**: The inclusion of real-time alerts required Dexcom to submit more detailed clinical trial data and usability studies, which extended the regulatory timeline compared to simpler systems like Abbott's Libre.

- **Higher Cost and Complexity**: Due to the advanced technology incorporated into Stelo, the approval process involved more complex risk mitigation plans, including post-market surveillance, which could introduce challenges during long-term monitoring.

In summary, while Dexcom faced some additional challenges in maintaining advanced features for Stelo, their strategy of leveraging existing approvals and adapting to OTC-specific requirements positioned them well to compete in the market.

IV. Patent Landscape Analysis

The continuous glucose monitoring (CGM) devices patent landscape shows an increasing patent activity in the last 10 years. Key players like Abbott Laboratories, Roche Holding AG, DexCom, Inc., and Medtronic PLC are heavily invested in securing intellectual property related to CGM technology. This section is a thorough review of the patent landscape, examining the patent holdings, technological trends, and competitive positioning of these and other companies in the CGM space. By analyzing patent families and overall document counts, we can identify key areas of innovation, such as miniaturization, improved sensor accuracy, and integration with insulin delivery systems among others.

This analysis will also include a comprehensive patent portfolio assessment of the top players, comparing factors such as their filing trends over time, the overall size of their patent portfolios, the geographic coverage of their patents, the average age of the patents in their portfolios, and the specific technologies they focus on.

Additionally, we will examine litigation trends to understand how these companies are leveraging their patents to protect their market share and gain a competitive advantage. These insights will provide a valuable understanding of the competitive dynamics and future direction of the CGM market.

1. Major Players in CGM

The CGM devices patent activity seems to be dominated by a handful of key players who have built up extensive patent portfolios. As the table shows, companies like Abbott Laboratories and Roche Holding AG lead the way with a large number of patent families, suggesting a broad scope of inventions and a strong position in various CGM technologies.

DexCom, Inc., while having fewer distinct patent families, displays the largest overall document count (total number of patent publications) hinting at a strategy focused on securing specific aspects of their technology with numerous patents.

Comprehensive Database of Continuous Glucose Monitoring Patent Assignees

Explore the patent families and global publications of leading companies and institutions in the CGM market.

	Assignee	Patent Families	Global Publications
1	Abbott Laboratories	173	827
2	Roche Holding AG	170	570
3	Medtronic PLC	161	592
4	DexCom, Inc.	148	1,148
5	i-Sens, Inc.	58	263
6	Insulet Corporation	56	148
7	Platinum Equity, LLC	53	127
8	Bigfoot Biomedical, Inc.	43	166
9	University of Virginia	41	154
10	Tandem Diabetes Care Inc.	40	121
11	Johnson & Johnson	36	99
12	Panasonic Holdings Corporation	35	181
13	Becton, Dickinson and Company	33	182
14	Novo Nordisk A.S.	30	96
15	Alphabet Inc.	27	76
16	Bayer AG	25	87
17	University of California	16	67
18	Cygnus, Inc.	16	59
19	OptiScan Biomedical Corporation	14	43
20	Chinese Academy of Sciences (CAS)	14	20

Additional 868 rows not shown.

Source: PatentVest • Created with Datawrapper

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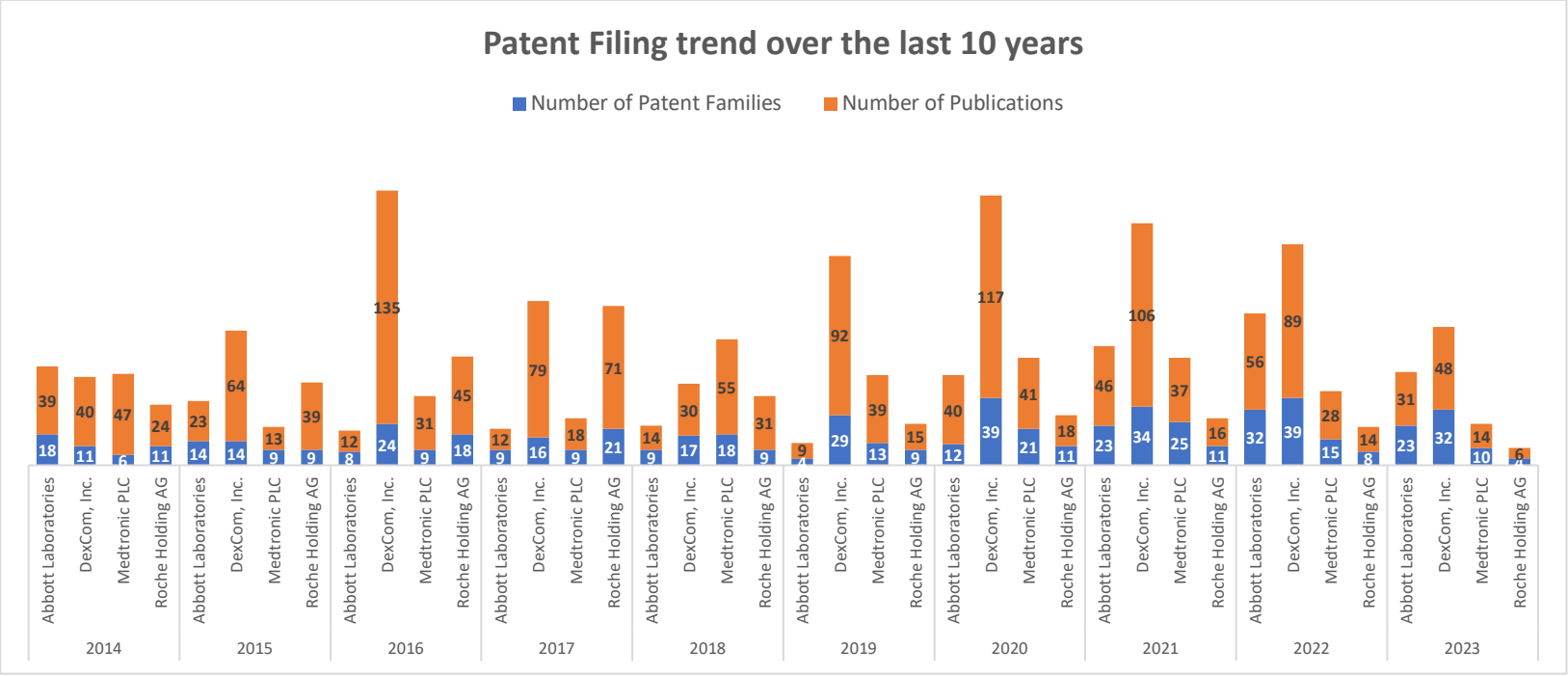
2. Comparative Patent Portfolio Analysis of Top Players

As mentioned above, this section will cover a comprehensive patent portfolio assessment of the top players, comparing factors such as their patent filing trends over time, the overall size of their patent portfolios, the geographic coverage of their patents, the average age of the patents in their portfolios, and the specific technologies they focus on.

2.1 Filing Trend



The chart above analyzes Dexcom's patent activity in relation to its main competitors: Abbott, Medtronic, and Roche. This comparison reveals several insights, such as:

Overall Trends

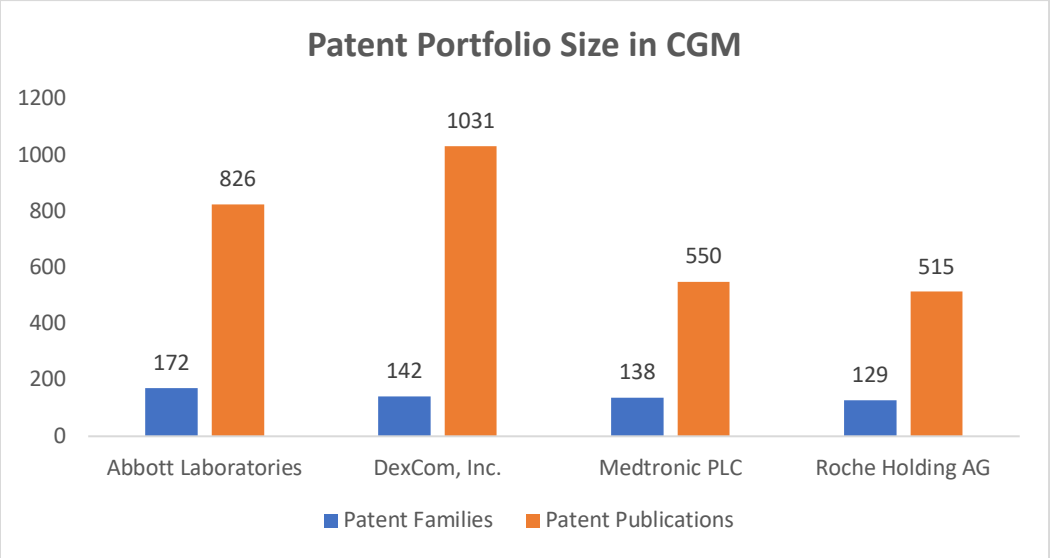
Increased Activity: All four companies show a general upward trend in patent filings, particularly in recent years. This highlights the growing importance of patents in this competitive and innovative market.

- **DexCom's Surge**: DexCom demonstrates the most aggressive patenting strategy, with a significant surge in filings, especially after 2019. This could indicate a focus on strengthening their IP position and potentially expanding into new areas within CGM technology.
- **Abbott's Consistency**: Abbott Laboratories maintains a relatively consistent filing trend, showcasing a sustained commitment to innovation and IP protection.

Company-Specific Observations:

- **Abbott:** While Abbott has a strong overall portfolio, their recent filings seem to prioritize quality over quantity, with a slight dip in total documents despite increasing patent families. This might suggest a focus on core technologies and key improvements.
- **Roche:** Roche displays a more fluctuating pattern, with peaks in 2017 and 2020. This could reflect shifts in R&D focus or responses to competitor activity.
- **Medtronic:** Medtronic shows a notable increase in filings around 2019-2021, possibly indicating a renewed push in the CGM space or a specific technological breakthrough.
- **DexCom**: DexCom's aggressive filing strategy, as mentioned earlier, is the most striking trend. Their focus seems to be on both breadth (patent families) and depth (total documents) of their IP protection.

2.2 Portfolio Size



The chart above illustrates the number of patent families and patent publications held by key players in the continuous glucose monitoring (CGM) device market.

DexCom, Inc. leads in total patent publications, aligning with their position as a major player in the CGM market. They are known for their innovative sensor technology and integration with smartphone apps. Their high patent publications count likely reflects a strategy of protecting various aspects of their devices and software, giving them a competitive edge.

Abbott Laboratories having numerous patent families is also understandable. While they are a broader healthcare company, their Libre system is a significant competitor in the CGM space. Their patent families might cover a range of technologies, from sensor design to data analysis algorithms, and potentially even manufacturing processes.

Medtronic PLC and Roche Holding AG, while having fewer patents, are still important players in diabetes management. Medtronic is a well-established medical device company with a strong presence in insulin pumps and other diabetes-related technologies.

Roche is a major pharmaceutical company with a focus on diabetes care, including insulin and diagnostic tools. Their CGM-related patents might be part of a broader portfolio aimed at integrated diabetes management solutions.

2.3 Jurisdictional Coverage

Global Patent Strategies for Continuous Glucose Monitoring

List of countries where Abbott Laboratories, DexCom, Inc., Medtronic PLC, and Roche Holding AG have filed patents and the number of filings in each jurisdiction.

Countries	Abbott Laboratories ▼	DexCom, Inc.	Medtronic PLC	Roche Holding AG
United States	147	130	113	97
WIPO	66	62	34	25
European Union	54	74	62	84
Canada	34	63	37	33
Australia	20	68	10	12
China	15	45	25	45
Spain	5	2		24
Germany	5	3	3	5
Japan	4	11	5	6
Austria	4	2	2	3

Additional 16 rows not shown.

Source: PatentVest, Inc. • Created with Datawrapper

This table above provides a snapshot of where leading CGM companies are focusing their patent protection efforts. It shows the number of patents filed in different countries by Abbott Laboratories, DexCom, Inc., Medtronic PLC, and Roche Holding AG, giving us insight into their global strategies for this important technology. As you can see, these companies prioritize key markets like the US and Europe, while also extending their reach to other regions.

It's clear that these companies are strategically protecting their CGM innovations in key markets. The US and Europe, being major healthcare markets with strong intellectual property protection, are understandably prioritized. However, the filings in China and Japan also highlight the growing importance of these markets and the companies' desire to secure their position in these regions.

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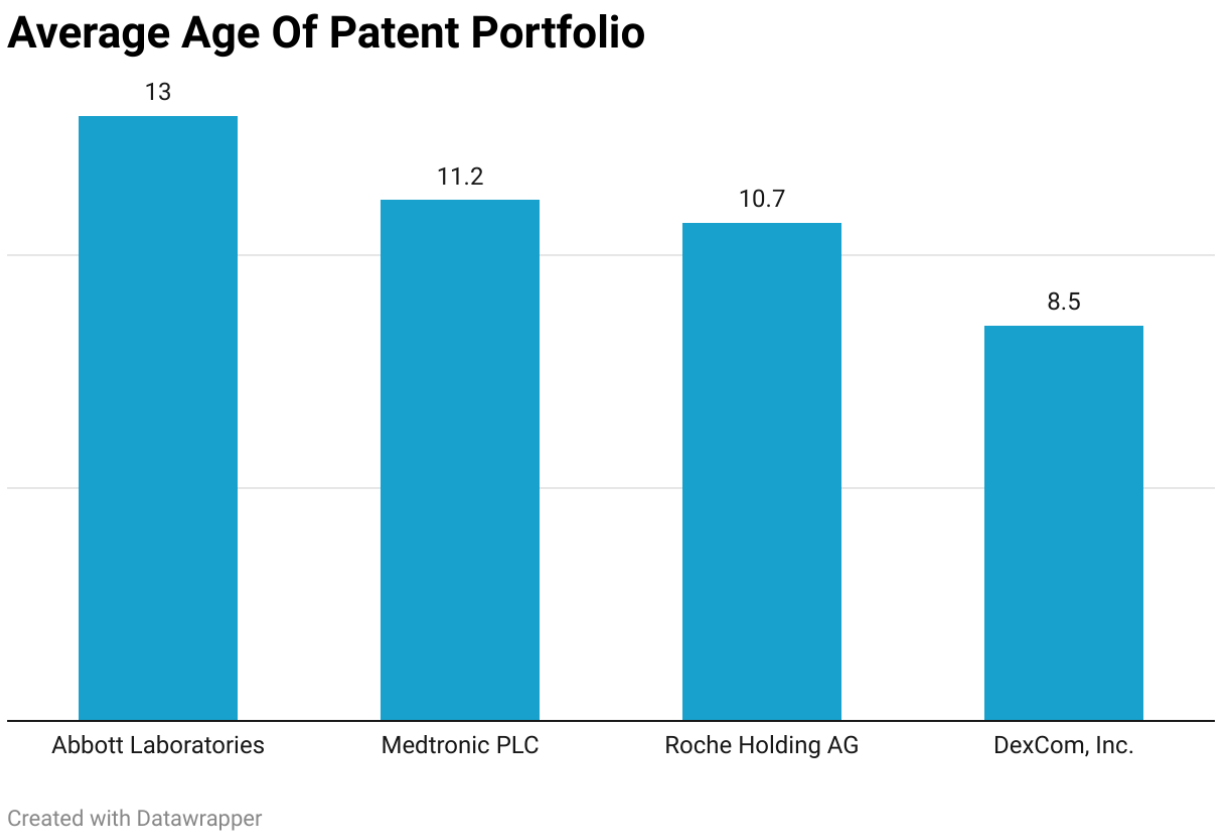
The variations in patent filings across countries likely reflect a combination of factors, including market size, regulatory environment, and the specific technologies being developed. For example, a company might focus more on patent protection in countries where it has a larger market share or faces greater competition.

2.4 Patent Age



This chart above gives us a quick snapshot of the average age of patents held by major players in the Continuous Glucose Monitoring (CGM) technology space.

Abbott Laboratories has the oldest patent portfolio, suggesting a long-standing commitment to innovation and a strong foundation of intellectual property. This could translate to a competitive advantage and potential dominance in the market.

DexCom has the youngest portfolio, indicating a more recent focus on CGM technology or perhaps a strategy of acquiring newer, cutting-edge patents. They might be rapidly innovating and pushing the boundaries of CGM technology.

Medtronic and Roche fall in between, with Medtronic having a slightly older portfolio. This suggests they both have established patent protection but are potentially less entrenched than Abbott.

2.5 Patent Litigation Review

In the patent landscape of the Continuous Glucose Monitoring (CGM) market, understanding the complexities of patent litigation is crucial when comparing competing companies. This section provides a snapshot of the ongoing legal battles between industry giants, examining key cases, outcomes, and their implications. By looking at these fights, we can see how companies try to protect their inventions, win market share, and influence the future of CGM technology. This analysis helps us understand the competition, risks, and opportunities for each company, giving us a better idea of how they might do in the future.

1. **Dexcom vs. Abbott**: The most prominent patent battles have been between Dexcom and Abbott. These two companies have been engaged in extensive patent disputes over their CGM technology. For example, in 2024, a case between Dexcom and Abbott over CGM patents saw multiple patent infringement claims. Both companies have accused each other of infringing on patents related to their CGM devices. In January 2024, a UK court found both Dexcom and Abbott patents invalid in a long-standing patent dispute over their CGM systems

   In the U.S., Dexcom filed lawsuits against Abbott for infringing several of its patents related to CGM systems. Abbott responded by filing inter partes review (IPR) petitions with the U.S. Patent Trial and Appeal Board (PTAB) to challenge the validity of Dexcom's patents. The litigation has spanned multiple jurisdictions, including the U.S., UK, and Germany, with both companies trying to protect their intellectual property while challenging the other's patents

2. **Medtronic**: While Medtronic has faced its own patent litigation issues in the broader medical device space, there is no recent prominent patent litigation solely focused on CGM systems that matches the intensity of the Dexcom-Abbott disputes. Medtronic has traditionally focused more on integrating its CGM systems with insulin pumps, which may reduce direct competition with standalone CGM devices like those from Dexcom and Abbott.

3. **Roche**: Roche, while also a significant player in the medical device market, has been less involved in high-profile patent litigation specifically related to CGM devices compared to Dexcom and Abbott. Roche has focused on its diabetes management platforms but has not been a central figure in the patent wars over CGM systems.

Dexcom vs. Abbott

1. 2014: Initial Settlement and Cross-Licensing Agreement
   Case: After years of patent disputes, Dexcom and Abbott entered into a settlement and cross-licensing agreement in 2014.

   Outcome: Both companies agreed not to sue each other over certain CGM patents during a specified "Covenant Period." This agreement allowed them to cross-license specific technologies and avoid further patent litigation for several years.

Significance: The agreement temporarily halted direct legal battles, although disputes resumed after the expiration of the Covenant Period

2. 2021: Dexcom vs. Abbott (Expiration of Covenant Period)
   Case: After the expiration of the "Covenant Period" in March 2021, Dexcom sued Abbott, alleging patent infringement related to Abbott's FreeStyle Libre CGM systems. Dexcom claimed that Abbott's products infringed on five of its patents.

   Outcome: Abbott responded by filing inter partes review (IPR) petitions to challenge the validity of Dexcom's patents. Dexcom sought a preliminary injunction to stop the IPRs but was denied by the court. The case was later transferred from Texas to Delaware for consolidation with other related disputes.
3. 2022: Abbott's IPR Petitions and Dexcom's Counterclaims
   Case: In April 2022, Abbott filed eight IPR petitions with the U.S. Patent Trial and Appeal Board (PTAB) to challenge the validity of Dexcom's patents. Dexcom responded with counterclaims, alleging that Abbott breached their previous agreement by filing the IPR petitions.

   Outcome: Dexcom's motion for a preliminary injunction was denied, and the case proceeded with further legal wrangling over the validity of patents. The PTAB did not immediately invalidate Dexcom's patents, and the IPR process continued.

4. 2023: Dexcom vs. Abbott in Delaware
   Case: After several procedural battles in 2022, the consolidated patent infringement and breach-of-contract case continued in the District of Delaware. Dexcom maintained that Abbott's FreeStyle Libre CGM systems infringed on multiple patents, while Abbott argued that Dexcom's patents were invalid due to prior art and other reasons.

   Outcome: The court did not immediately rule in favor of either party, and the litigation process continued into 2024.

5. 2024: Dexcom vs. Abbott (UK Trial)
   Case: In January 2024, a UK High Court trial saw both Dexcom and Abbott argue over the validity and infringement of several CGM-related patents. Abbott claimed that Dexcom's G6 and G7 devices infringed on Abbott's patents, while Dexcom argued that Abbott's patents were invalid due to prior art and lack of novelty.

   Outcome: The court found both Abbott's and Dexcom's patents invalid, leading to a stalemate. While this ruling did not provide a decisive victory for either party, it set the stage for further litigation in other jurisdictions such as Spain and Germany.

6. Ongoing Litigation: 2024 and Beyond
   Case: Both companies are still involved in patent disputes in multiple jurisdictions, including Germany, Spain, and before the Unified Patent Court (UPC). These cases largely center on the same patent portfolios and infringement claims that have been litigated since 2021.

Outcome: As of early 2024, no final resolution has been reached. The litigation is expected to continue, given the high stakes in the expanding CGM market.

2.6 Technology Focus

Abbott:
Focus: Enhancing accuracy and integration with insulin delivery systems.
- Examples:
  - US11957463B2 - Improving the accuracy of continuous glucose sensors using dynamic outputs.
  - US11967408B2 - Method and system for providing integrated analyte monitoring and infusion system therapy management.

Notable Trend: A focus on closed-loop systems where glucose monitoring directly informs insulin delivery for tighter control.

Dexcom:
Focus: Improving sensor design, data utilization, and user experience.
- Examples:
  - US12009580B2 - Antenna configuration for compact glucose monitor.
  - US11998322B2 - Systems and methods for intermittent glucose monitoring.
  - US11990238B2 - Decision support and treatment administration systems, potentially incorporating hormonal cycle information.

Notable Trend: Exploration of more flexible monitoring options (intermittent) and personalized data analysis for improved decision-making.

Medtronic:
Focus: Improving sensor technology, data analysis, and closed-loop systems. Advancing closed-loop systems and insulin delivery technology.
- Examples:
  - US11974844B2 - Sensor systems, devices, and methods for continuous glucose monitoring (Using electrochemical impedance spectroscopy (EIS) to improve sensor data reliability and calibration.)
  - US11974863B2 - Glucose estimation without continuous glucose monitoring. Developing methods for glucose estimation without continuous glucose monitoring, potentially using intermittent measurements and other data sources
  - US11931145B2 - Orthogonally redundant sensor systems and methods.
    Exploring orthogonally redundant sensor systems with both optical and non-optical glucose sensors for improved accuracy.

Notable Trend: A focus on refining sensor technology, expanding data sources for glucose estimation, and developing more robust closed-loop systems.

Roche:
Focus: Developing advanced algorithms and systems for continuous glucose monitoring data analysis and management.
- Examples:

- US11998321B2 - System and a method for automatically managing continuous glucose monitoring measurements indicative of glucose level in a bodily fluid.
  A system for automatically managing continuous glucose monitoring measurements, potentially incorporating behavioral sensor data.
- US11925462B2 - System and method for analyzing glucose monitoring data indicative of a glucose level, and a computer program product.
  A system for analyzing glucose monitoring data to provide insights and potentially guide treatment decisions.
- US11877869B2 - Method and system for determining a carbohydrate intake event from glucose monitoring data indicative of a glucose level, and a non-transitory computer readable medium.
  A method for determining carbohydrate intake events from glucose monitoring data, which could be used to improve dietary recommendations and glucose control.

Notable Trend: Roche is focusing on sophisticated data analysis techniques to extract meaningful insights from continuous glucose monitoring data and provide more personalized diabetes management solutions.