Published by :
http://www.ijert.org

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 13 Issue 06, June - 2024

Smart Pills and Ingestible Sensors for Real-Time Health Monitoring: A Patient Landscape and Over View

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Abstract:
The modern healthcare landscape is intricately linked to the advancement of digital health tools, with digital pills integrated with ingestible sensors representing a transformative innovation. This paper provides a comprehensive analysis of the patent landscape surrounding these digital pills, focusing on trends in patent protection, leading innovators, therapeutic areas of interest, and future prospects. Systems like MyTMed, which include a digital pill with a radiofrequency emitter, a relay hub, and a cloud-based server, demonstrate the potential of digital pills to enhance treatment outcomes by fostering patient compliance, reducing hospital admissions, facilitating mobile clinical monitoring, and lowering treatment costs. A thorough investigation conducted database showed an increase in patent applications concerning ingestible sensor-equipped digital pills. Intelligent medication delivery methods, mobile clinical monitoring, and endoscopic diagnostics are the main areas of innovation. In terms of patent issuance, the US, the EPO, Canada, Australia, and China are in the lead. Mental health, HIV/AIDS, pain management, cardiovascular care, diabetes management, gastroenterology, oncology, TB, and transplantology are important therapeutic fields. Though digital pills have great promise, ethical issues are raised by the focus on income creation and compliance monitoring, raising questions about patient autonomy, privacy, and shared decision-making. To ensure patient rights, more precautions must be taken. This study emphasises the need for strong frameworks for the effective deployment of smart pills and ingestible sensors, pointing out the opportunities and problems in the patent environment. It also signals a trend towards personalised, real-time health monitoring. Patient outcomes and safety are expected to significantly improve with the integration of these technologies into healthcare systems.

Keywords: **digital medicines, sensor-integrated pills, patent landscape, treatment compliance, digital medication, medication adherence, real-time health monitoring, privacy concerns, technological breakthroughs, and the use of intellectual property in healthcare.**

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1. INTRODUCTION

In the present world, the creation of digital health tools and solutions is closely related to the advancement of the healthcare system. Digital tablets that are combined with edible sensors are one of these advances; they are a cutting-edge class of medications that have the ability to change lives. In light of its ability to support health promotion, uphold international security, and offer services to vulnerable people, digital technologies are critical to the future of global health, according to the World Health Organization's (WHO) worldwide policy.

Integrated sensors in digital pills, sometimes referred to as smart pills or smart medication, enable software on tablets and smartphones to communicate with the device to monitor pharmacotherapy. This feature is essential since drug opt-out, or low patient adherence, is a significant problem in all fields of medicine. Conventional tools, such pillboxes with the days of the week written on them, have not worked well to prevent amnesia. Regardless of the cause—simple human error or severe mental illness, this omission has major ramifications for individuals following strict pharmaceutical regimens.

Many healthcare professionals prefer the term "adherence" over "compliance" since the latter implies that the patient is only following orders without question and that the treatment plan is not predicated on a therapeutic alliance or contract that the patient and the doctor have built. Both words provide incomplete and misleading explanations of the behaviour of taking medications.

By removing the necessity for invasive procedures or large external monitoring devices, digital pills offer major advantages over previous techniques. This improvement facilitates a more proactive and individualised approach to healthcare by improving patient comfort and enabling continuous and accurate surveillance of physiological changes. These state-of-the-art gadgets are packed with sensors and microchips to gather vital health information including body temperature, heart rate, and digestive system activities. The data collected is wirelessly transferred to a smartphone or additional gadgets, allowing patients and medical professionals to track health indicators in real time.

The real-time data on drug intake events, ingestible biosensor systems have been introduced as a remedy to medication adherence problems. These technologies provide discreet, direct proof of medicine intake and can be easily integrated into current prescription regimes. With the use of this real-time monitoring feature, adherence data may be contextualised within a patient's regular activities, facilitating pertinent and timely responses. An ingestible biosensor system called My/Treatment/Medication (MyTMed), for instance, is intended to enhance real-time antiretroviral therapy (ART) adherence in people who use stimulants for HIV infection. These individuals frequently struggle with consistent ART adherence, which can result in disease progression and higher rates of drug resistance.

Digital pills have a lot of promise, but there are still a lot of obstacles in the way of their broad use in medicine. These include concerns about treatment costs, confidentiality, safety, and therapeutic efficacy. Further study in this field is necessary, as seen by the unestablished patent landscape for digital pills with ingestible sensors.

The creation of digital medicines depends heavily on patent documentation, a priceless source of data that illustrates the innovation process. Patent analysis is an essential instrument for comprehending technical trends and market processes because of the universality of patent data, which is guaranteed by the standardisation of standards for presenting intellectual property data, and the dependability offered by the state registration of intellectual property rights. In order to provide academics, developers, and policymakers interested in the future of health monitoring technologies with useful information, this study analyses the patent landscape of ingestible sensors and smart pills for real-time health monitoring. We aim to discover the major players influencing this field's development and unearth the technological breakthroughs propelling it through a thorough examination of patent filings, trends, and significant inventions.

2. DIGITAL HEALTH: A MORE COMPREHENSIVE VIEW

Immersion in the realm of digital health is akin to entering a futuristic healthcare environment, where wellness and technology coexist harmoniously to optimise patient outcomes. The field is full of innovative tools and technology that aim to

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 13 Issue 06, June - 2024

improve healthcare accessibility, individualization, and—dare we say it—enjoyability. It goes well beyond traditional medical treatments.

Imagine carrying a personal wellness consultant with you at all times, discreetly recording your heart rate, steps taken, and even the quality of your sleep, on your wrist or in your pocket. That's the beauty of wearable gadgets and medical apps, that have become our dependable allies, encouraging us to make healthy decisions and watching out for symptoms that may indicate a visit to the doctor. Then there's telehealth, a game-changer that knocks down walls and distances, bringing the doctor's office to our living rooms. It's not just about convenience; it's about making sure everyone, no matter where they live, has access to quality healthcare. Whether it's a video consultation with your GP or a virtual therapy session, telehealth ensures you're never too far from the care you need. Behind the scenes, electronic health records (EHRs) and health IT systems are the unsung heroes, organizing our health histories with the precision of a librarian. They make sure that when different doctors are piecing together our health puzzles, everyone has the right pieces.

The approach that we perceive healthcare is being revolutionised by digital health. These days, the focus is not only on curing diseases; it's also on preventing them, improving our knowledge of them, and tailoring treatment to each individual's needs. With information and modern technology at our disposal, we are active players in determining our own health and wellness as we continue on our digital health journey rather than only being recipients or figures in a system. In the future, healthcare will be more than just a service; it will be a collaboration between technology and people that will make us all happier and healthier.

Fig.1: Ayushman Bharat Digital Mission

3. DIGITAL PILLS: THE PRESENT AND THE FUTURE

Patients on a prescribed regimen frequently harbour questions and concerns about whether or not they took their prescription. Medication non-adherence is more common than we may think; worldwide, adherence rates range from 25% to 50%. Because of a critical flaw, traditional interventions like pillboxes with the hours of the week labelled on them have not been able to effectively address this issue: they are unable to prevent amnesia. Ignorance, whether due to human error or severe mental illnesses, can have detrimental effects on patients following a strict drug regimen.

Digital pills provide real-time information regarding drug ingestion by sending information to an exterior device, like a smartphone or cloud-based server. Thanks to this technology, medical professionals may precisely track patients' compliance with their recommended treatment plans. Furthermore, digital pills can notify patients and carers in the event that a dose is missed, which lowers the possibility of non-adherence brought on by forgetfulness. For the management of chronic illnesses, when continuous drug adherence is essential for optimal therapy, this real-time monitoring capacity is especially helpful.

Ingesting sensors for health monitoring seems to have a bright future. We anticipate that future technical developments will enhance sensor accuracy, dependability, and biocompatibility, leading to a rise in their use in clinical settings.

Ingesting sensors has potential applications that go beyond treating specific patients. With the use of this technology, large-scale research to monitor disease outbreaks and pinpoint risk factors could completely transform public health. Additionally, by continuously monitoring drug safety and efficacy during clinical trials, these sensors may have a big impact on drug development. The potential of artificial intelligence (AI) and machine learning algorithms to transform personalised medicine has been boosted recently by their integration with ingestible sensor data. This allows for personalized therapy recommendations and predictive analytics based on real-time health data.

5. MY TMED SETUP

To track and assist with medication adherence, MyTMed combines a variety of cutting-edge mobile technology with dynamic, personalised behavioural therapies. The digital pill that powers MyTMed is just a regular gelatin pill capsule with an exclusive RF emitting tag attached to it.

The study drug is released into the stomach when the patient consumes the digital tablet, causing the gelatin capsule to dissolve. The tag emits a distinct radiofrequency signal upon contact with gastric pH, which is then transmitted to a hip-mounted receiver known as The Hub. The Hub serves as a relay, sending a data packet, complete with ingestion time and event, to a cloud-based web server that complies with HIPAA regulations via short messaging system (SMS) protocols. A patient-facing interface interprets data from the cloud-based web server, enabling real-time communication between patient-physician pairs regarding adherence and nonadherence. Unique transmission from the digital pill's RF tag correlates with the co-encapsulated drug. Should a patient swallow two digital pills simultaneously, the Hub will detect two distinct radiofrequency signals, indicating two distinct ingestion occurrences. The digital pill passes through the gastrointestinal tract and the insoluble RF tag is eliminated during around 30 minutes of radiofrequency transmission.

5.1 Radiofrequency radiation does not modify the structure of drugs.

Prior to the co-encapsulated drug being acquired by the Hub, the digital pill's current RF signals will pass through it. It has remained theoretically baseless to worry that radio waves could change the chiral content or chemical structure of

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 13 Issue 06, June - 2024

pharmaceuticals. Research using radiofrequency waves to administer insulin and chemotherapy has not revealed any changes to the structural makeup of the drugs.

5.2 Radiofrequency tag including gelatin capsule dissolution

The potential for changes in drug solubility, pharmacokinetics, and pharmacodynamics arises when pharmaceuticals are encapsulated in gelatin capsules. Gelatin capsules have the potential to function as a barrier, blocking access to the stomach pH needed to breakdown a drug. Gelatin capsules do not appear to change the pharmacokinetics or pharmacodynamics of a drug that is encapsulated, according to a number of lines of research. First, gelatin capsules quickly dissolve in an aqueous medium and are commonly employed in pharmaceutical formularies. Second, there is no evidence that changing the gelatin capsule form of Antiretroviral Therapy (ART) drugs, including saquinavir, affects the drug's pharmacodynamic properties. Third, saquinavir and L-thyroxine's palatability has been increased with the use of gelatin capsules, all without a noticeable impact on pharmacodynamics.

5.3 Radiofrequency tag including gelatin capsule dissolution

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6. CONSIDERING DESIGN IN INGESTIBLE BIOSENSOR SYSTEMS

6.1 Technical Points to Remember

MyTMed relays ingestion data via the Hub to the cloud-based interface using SMS protocols. Other systems connect the medicine consumption event to a functional interface that facilitates patient-physician interactions by means of ambient wireless local area networks (WiFi). MyTMed can operate in low resource locations with weak WiFi access by sending SMS via the control channel included in the majority of mobile phones and smartphones. Despite the fact that applications for smartphones have been created to promote medication adherence, research participants may find out about the existence of these apps on their device in the event of theft or unauthorized access. SMS/MMS protocols allow for the transmission of interventions that are useful even in low-power scenarios because they use less power than applications. In order to prevent breaches and unauthorised access to protected health information (PHI), novel mHealth solutions need to be well secured. The consumption data packets from the RF sensor, SMS relay to the cloud-based server, and interventions delivered via the interface are examples of potential sources of data acquisition for an ingestible biological sensor system. Using unique radio frequencies to conceal ingesting data, putting the Hub close to the electromagnetic signal to reduce transmission distance and interception risk, and crafting customised intervention messages are some techniques to reduce security breaches.

6.2 Requesting Patient Involvement in a Real-World Situation

To avoid participant detection, smartphone applications and edible biosensor components used in real-world settings should be kept covert and subtle. Smartphone apps that track medicine adherence, exposed radiofrequency-tagged digital tablets, and relay devices can all provide indicators that a patient is engaging with an ingestible biosensor. Patients who want the confidentiality of their medicine intake or sickness may suffer if this information is disclosed. We've done a number of things to make MyTMed both useful and inconspicuous. Firstly, the radiofrequency tag is hidden by the use of an opaque gelatin capsule, which keeps the patient's involvement in a medication adherence trial from being discovered. Second, in the event that the patient's phone is stolen, the MyTMed interface will continue to operate via SMS (text messages) and MMS (multimedia pictures) signals, eliminating the need for an app. Third, participants choose and customize the MyTMed intervention messaging. Text and multimedia messages can contain unrelated content that the user recognises as a trigger to access adherence information. They are also anonymous and confidential.

6.3 Acceptance of Patients

The acceptance and usage of the digital pill and Hub by patients is essential for the effectiveness of an ingestible biological sensor system such as MyTMed. Patients who have mistrust for the healthcare system are probably more prone to not take their medications as prescribed and might not want to use ingestible monitoring devices. Patients who have a history of nonadherence and mistrust of the healthcare industry are likely to adopt MyTMed, according to multiple lines of data. First, drug users who are HIV positive have said they would embrace monitoring technologies if anonymity is guaranteed. Second, an ingestible biosensor given in addition to antipsychotic drugs proved successful in a pilot research, which included 96% of individuals having schizophrenia or bipolar disorder. Third, patients with

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
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previous histories of cocaine consumption have embraced and found success with the use of wearable biosensors.

7. THE INTERFACE OF MYTMED

A sophisticated bidirectional technology called the MyTMed interface enables patient-physician pairs to work together in real time to enhance ART adherence. The interface uses Health Level-7 (HL7) communication via Mirth to retrieve adherence and nonadherence reports directly from the cloud-based server. Through HL7, a hub's unique ingestion information and timestamp related to a single patient are downloaded, and Mirth interprets them. In order to create bidirectional messages with text and multimedia for patient-physician tandems to transmit instances of adherence and nonadherence, this data is kept and evaluated on a secure database.

7.1 Behavioural Approaches to Encourage Adherence

The application of long-term therapies in a mobile situation is not well supported by behavioural theories. The informational-motivational-behavioral (IMB) paradigm serves as the foundation for the interventions in MyTMed. The IMB model first emerged for interventions aimed at reducing HIV risk. Using this paradigm as a guide, interventions offered behavioural skills necessary for risk reduction after first educating participants about HIV transmission and then motivating them to reduce their risk. Since then, behavioural research has successfully and extensively used it, notably to increase ART adherence. MyTMed, which is based on the IMB framework, provides accurate and up-to-date information about medication adherence and offers an intervention designed to increase personal motivation to enhance adherence behaviour. Our intervention is offered in a dual stage procedure intended to maximise acceptability and adoption in order to seamlessly integrate the IMB method to the mobile environment. This technique, known as the "teaser and tie-in," enables us to present factual and motivating material that is supported by research and will cause behavioural change. A text message and a multimedia image are combined to create a teaser that will draw in participants. Focus groups consisting of methamphetamine users infected with HIV will decide the teaser's content, giving them a unique taste. The participant is taken to a tie-in—a second image with a personalised, meaningful topic that illustrates the effects of adhering to art—after clicking on the teaser. In order to promote or sustain behaviour change in the form of ongoing medication adherence, Tieins will include both motivating and educational content.

8. CONSEQUENCES FOR MEDICAL TREATMENT

For patients who use digital tablets, the reminder system—which can verify that a pill was indeed taken—is the main advantage. Similar functionality could be offered via a straightforward alert or "nudge." But the price of digital pills is far more than that of their non-digital, generic equivalents. Furthermore, there's a chance that patients will grow too dependent on these tools and lose sight of possible problems, including a broken cell phone or additional problems. Such malfunctions could lead to patients overdosing if the gadget malfunctions to register previous intake of medication or skipping doses if it signals mistakenly that a pill is already taken.

An further group of concerns pertaining to digital pills is the automated gathering and dissemination of patient information. Significant questions of privacy, coercion, monitoring, and autonomy are brought up by this. Controls on digital medications must take these issues of autonomy seriously. Three main categories can be used to group patients: competent, inept, and "socially dangerous." Crucially, unless demonstrated differently, an adult is deemed capable. Although mental health disorders may affect an individual's competence, it is not a given that people with mental health disorders are incapable of making decisions. Competent professionals should evaluate a candidate's legal ability on an individual basis.There is no agreement on how to operationalize the assessment of decisional competence in mental patients or set basic norms, despite the fact it is commonly known that this process is difficult. Competency depends on the circumstances, and the evaluation criteria are influenced by how difficult the decision is. Assessing a person's ability to make decisions should be based more on the principles at play and the effectiveness of the decision-making processes than on whether or not the conclusion seems foolish or irrational to other people. Furthermore, capacity varies with time and is task-specific and dynamic.

Though these practices remain controversial from an ethical and legal standpoint, particular people with mental illness may be legally forced or permitted to receive specific kinds of mandatory treatment, including outside of a hospital setting. It's also critical to emphasise that, in the environment of psychiatry, people who identify as Black, Indigenous, People of Colour (BIPOC), or disabled, are especially susceptible to systemic racism and discrimination. These populations experience a disproportionate amount of coercive mental health treatments, and the criminal justice system frequently pathologized them. With regard to digital psychiatric medications, the surveillance issue is particularly relevant because these technologies have the potential to worsen already-existing disparities.

A better and more patient-centered healthcare experience is being created by the digital health wave, which is changing healthcare for patients in ways only science fiction could have ever dreamed. Imagine a world in which, no matter where you are, you can always video contact your doctor and have your medication inform you time to take it. The medical profession is undergoing a revolution as digital health holds great promise for all parties concerned.

This revolution is led by smart pills, which answer the age-old query, "Did I consume my prescribed medicine today?" With real-time information, these tiny technical marvels connect directly with medical personnel to keep treatments on schedule. They serve as a discreet reminder system and guarantee that prescription schedules are followed, much like a portable medical companion.

Patients are also being given more control over their health through wearable technology and health applications. These devices convert routine actions into useful health data by tracking steps, keeping an eye on heart rates, and possibly analysing sleep patterns. This continuous feedback loop can help people lead

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
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better lives by identifying any health problems before a trip to the clinician is required.

Digital health is about putting people at the centre of their healthcare journeys, not only about high-tech devices and software. It seeks to improve accessibility, personalisation, and responsiveness of care. It is clear as we traverse this new electronic healthcare landscape that technology is becoming essential to living well—rather than just helping with health. With the incredible possibilities of digital health technologies, the future of healthcare looks to be centred on wellness maintenance.

Real-time health monitoring, better patient care, and improved drug adherence are just a few of the advantages that come with digital pills and other electronic wellness devices. But they also bring with them difficulties that need to be resolved. The secret to effectively integrating new technologies into medical systems is to strike a balance between their benefits and the practical and ethical issues. Realising the full potential of digital health solutions to improve healthcare requires ensuring that they are equal, accessible, and cognizant of patient autonomy.

It is critical to guarantee that patients maintain ownership over their health information and make knowledgeable decisions about their care.

Furthermore, great thought needs to be given to the ethical ramifications of employing digital tablets in mental health treatment. There is cause for worry regarding the possibility of coercive use of these technologies, particularly against marginalised communities. Making sure that the use of digital health tools doesn't worsen already-existing disparities or support institutionalised prejudice is crucial.

8.1 Security and Privacy of Data

The security of private health information is crucial in this day and age when health data is digital. The potential for data breaches is somewhat concerning because it can have a substantial impact on people's privacy and well-being if unauthorized parties gain access to confidential health information. Patient data must be protected by strong cybersecurity measures and stringent adherence to laws such as HIPAA in the United States.

8.2 Parity and Availability

Adoption of digital health solutions across the board is still obstructed by the digital divide. In order to take use of telehealth services and health monitoring apps, not everyone has equal access to the internet or digital devices. For health inequalities to not worsen and for advancements in digital health to be inclusive and equitable, it is imperative that this disparity be addressed.

8.3 Knowledgeable Consent

As digital health technology advances, getting informed consent is becoming more difficult. Patients need to be completely informed about the data being gathered, its intended purpose, and the individuals who will have accessibility to it. Respecting the autonomy and rights of patients requires ensuring that the consent procedure is clear and understandable.

8.4 Algorithmic Prejudice

Although AI and machine learning are essential to many health care solutions, prejudice can still affect them. Algorithms may reinforce or even worsen health inequities if the training data isn't diversified. To guarantee that digital health solutions are equitable and successful for all populations, developers must give top priority to incorporating a variety of data sets.

It will need a team endeavour from technology developers, medical professionals, legislators, and patients to overcome these obstacles. We can fully utilise digital health technology to revolutionise medical treatment in a way that is safe, just, and considerate of patient rights by tackling these ethical issues head-on.

8.5 Reasons for Forgetting

There are various hypotheses that explain why forgetting happens, but it is a normal aspect of the memory process. Comprehending these hypotheses, in conjunction with acknowledging forgetfulness as an advantageous cognitive function and pinpointing the elements that lead to memory impairment, offers valuable understanding of the intricacies of human reasoning.

10. SMART PILL MECHANISMS AND TECHNOLOGIES

Smart pills are leading the way in the rapidly changing field of healthcare by fusing the fields of pharmacology, micro tech marvels, and biomedical science. Imagine taking a pill—but not just any pill—that is intelligent enough to communicate with the physician or smartphone directly about your personal health secrets. This is the magic we are discussing: a small, ingestible gadget that is revolutionising the way we track our health, make sure we take our medications, and even identify and treat internal ailments.

How does all this valuable information go from a pill that is roving about your body to a place where it is needed? These pills will introduce you to the world of microelectronics, which uses radio frequencies to transmit low-energy signals that are encoded with your body's secrets. To ensure the data lands safely on external devices like patches, your phone, or specific health monitors, some even use your body as a conductor to spread the word.

One of the greatest innovations in smart pill technology is the PillCamTM, which circumvents the discomfort of previous methods to provide a less intrusive look at the health of your colon. As we turn our attention to the future, the possibility of intelligent tablets that can precisely determine when and where to release medication in response to your body's signals looms, opening the door to efficient and successful medical interventions.

Essentially, smart pills are changing not just the pharmacy but also our connection with medicine by increasing the precision, knowledge, and personalisation of every diagnosis, treatment, and health choice.

11. MATERIALS AND PROCEDURES

The patent search was conducted using the following keywords: digital pill, smart pill, ingestible sensor, and their combinations. The search terms were Global Patent Classification as well as Cooperative Patent Classification combined with the title, abstract, and assertions fields. Keyword research is useful while

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seeking patent-related information. But analysis is difficult and time-consuming because a lot of data is associated with a large number of keywords and their synonyms. Focusing the search makes it faster and more clear thanks to the usage of language-neutral patent classification. Therefore, investigations looking at the patent landscape produce better results when the keywords and codes from the Cooperative Patent Classification and the global Patent Classification are combined.

Digital items were deemed outside the purview of this work and excluded from the study, which include subcutaneous and implanted sensors enabling continuous glucose tracking systems.

12. RESULT AND DISCUSSION

To assist patients in taking their prescriptions as directed, MyTMed is a cutting-edge medication adherence solution that is simple to integrate into already-existing body sensing networks. The majority of current adherence metrics are based on indirect measures of consumption. By using a digital pill, MyTMed eliminates recollection bias or distortion by recording drug ingestion at the exact moment it occurs. Improved interventions and methods to maintain medication adherence can be designed with better evidence of drug consumption.

More than The MyTMed method makes it simple to encapsulate a drug, which enables us to refine our concept over time for a range of chronic illnesses. Our idea is interesting and workable, but it has a few drawbacks. We have not yet implemented our MyTMed conceptual framework in an actual environment. Based on past conversations with our research population (users of stimulants who are HIV positive), we expect patients to accept MyTMed.

The IQVIA Digital Solutions database systematised the various kinds of digital healthcare solutions. As of the end of June 2021, there were 122 digital care products and 137 digital treatment products at various phases of development. Out of all the so-called Digital Therapeutics, twenty-five had obtained market authorization and were cleared to go on sale by way of regulatory procedures. Nine of the twenty-five Digital Therapeutics with at least one market authorization were in the United States, nine were in Europe, and one was in Japan, with some overlap.

To pinpoint the most significant advancements in the industry, a comprehensive examination and organisation of the worldwide patent protection of digital tablets using ingestible sensors was carried out.

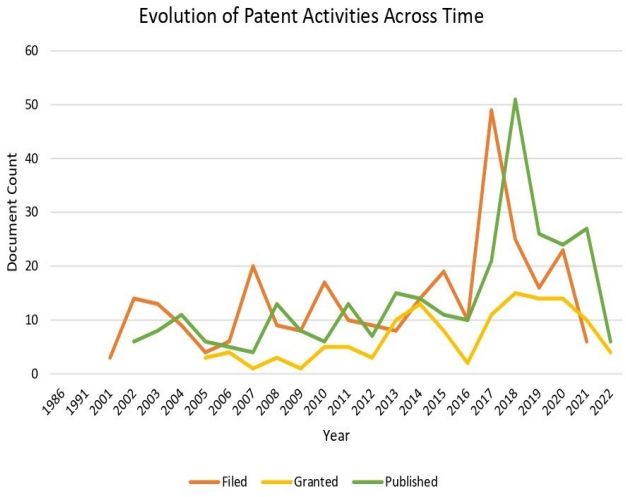

Fig.2: Evolution of Patent Activities across Time

A steady increase in the quantity of applications and issued patents was noted between 2010 and 2018. The bulk of applications were filed in 2017 and a significant number of patents were granted in 2018. The lower level of patent activity over the initial half of 2019–2022 may be due to a priority for commercialization and the entry of currently developed ideas into markets rather than to the filing of new patents.

The landscape of patents provides compelling evidence of scientists' ongoing efforts to produce digital pill forms. It should be mentioned that a few of the patents have expired. Patents are rarely maintained in effect for the full 20 years (25 years for pharmaceuticals) due to the rapid advancement of technology and its replacement by newer, more advanced ones. The majority of the examined patents were submitted between the years 2000 and 2018.

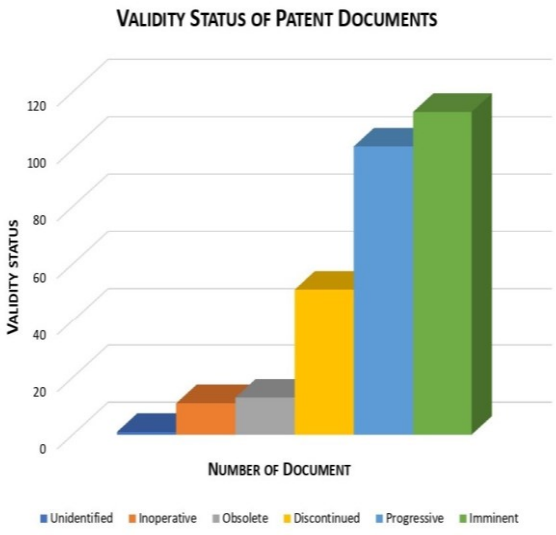

Fig.3: Validity Status of Patent Documents

International Journal of Engineering Research & Technology (IJERT)
ISSN: 2278-0181
Vol. 13 Issue 06, June - 2024

The European Patent Office, The United States, Canada, China and Australia are the top countries in the world in terms of patent issuance; between them, they hold 72% of all patents worldwide. The primary patent owners in the field of ingestible sensor-equipped digital pills are depicted in Figure.3 Among the leading businesses dedicated to growing the size of the digital pill market through inventive development are Proteus Digital Health Inc. (Redwood City, CA, USA), Otsuka Pharmaceutical Co., Ltd. (Tokyo, Japan), Given Imaging Ltd. (Yokneam, Israel), Pop Test Abuse Deterrent Technology LLC (Cliffside Park, NJ, USA), Given Imaging Inc. (Duluth, GA, USA), Innurvation Inc. (Glen Burnie, MD, USA), Otsuka America Pharmaceutical Inc. (Rockville, MD, USA), Progenity Inc. (San Diego, CA, USA), Pop Test LLC (Cliffside Park, NJ, USA), The Smart Pill Corporation (Buffalo, NY, USA), and others.

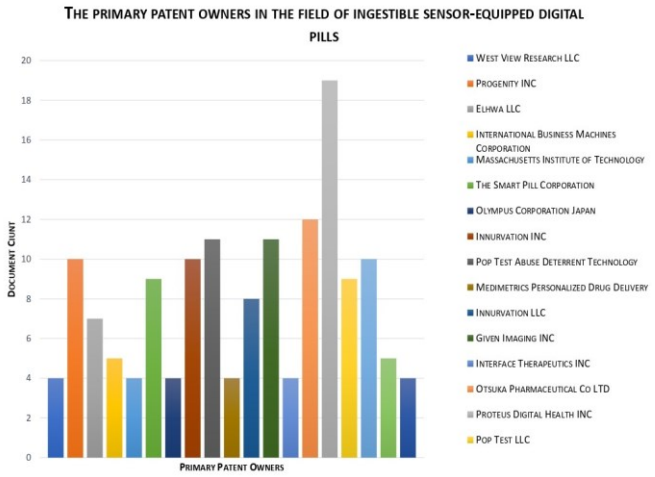

Fig.4: Primary Patent owners in the field of Ingestible Sensor-Equipped Digital Pills

Their innovations include in the areas of smart drug administration, endoscopic diagnostics, and mobile clinical monitoring. Digital tablets with sensors are used in mobile clinical monitoring and smart drug delivery, which can be used to treat a variety of ailments in a broad patient population. Diagnoses including persistent constipation, nausea, acid reflux, gastroparesis, colon cancer, and other issues with gastrointestinal peristalsis can be made with the aid of a capsule endoscopy. It should be mentioned that the current cost of digital pills with ingestible sensors is high, and regulatory approval requirements for new products are stringent. Scientists are actively working in this field to introduce safe and effective digital medicines to the healthcare industry within this framework.

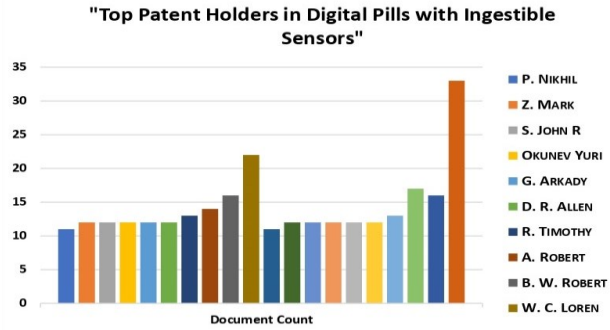

Fig.5: Top Patent Holders in Digital Pills with Ingestible Sensors

Proteus Digital Health (Redwood City, CA, USA) is among the top innovators in the development of ingestible sensor systems for medication adherence, according to the report. With the help of Proteus' unique digital pill system, treatment plans can be customized with broad potential advantages across a range of therapeutic domains. Otsuka Pharmaceutical Company (Tokyo, Japan) developed the medication Abilify MyCite using a digital ingestion tracking system—a sensor called a "Ingestible Event Marker"—manufactured by Proteus Digital Health.

Abilify MyCite is a unique antipsychotic containing an ingestible sensor that is used to treat adult depression as an adjunctive medication as well as people with schizophrenia and manic and mixed episodes linked to bipolar I disorder. Adherence to a therapeutic plan is a major issue in the context of psychotropic medication treatment. Antipsychotic side effects, which might include weight gain, sexual dysfunction, nausea, vomiting, and altered doses or cessation of medication, can be quite distressing. Since its discovery by Otsuka Pharmaceutical in 1988, aripiprazole—the main chemical component of Abilify—has been approved by the FDA as an antipsychotic. It became available as a generic medication in 2015.

For the first time, a digital medicine system was approved by the FDA in 2017 with the Abilify My-Cite (aripiprazole tablets with sensor), an oral medication–device combination product that combines an Ingestible Event Marker sensor with aripiprazole tablets.

The drug, that includes the active substance aripiprazole; a sensor that sends a signal to a patch placed on the "lower edge of the rib cage"; a smartphone app; and an internet portal are the four main components of Abilify MyCite that communicate with each other through Bluetooth technology. The tablet has a built-in 1-mm sensor. Composed of silicon, magnesium, and cuprous chloride (copper), it alerts the patch to the presence of stomach acid. The magnesium and cuprous chloride in the sensor react when they come into touch with stomach acid, turning on and powering the gadget and sending a signal to the patch that tracks ingestion. After that, this data is sent to the smartphone app.

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ISSN: 2278-0181
Vol. 13 Issue 06, June - 2024

The pharmacologically active substance aripiprazole, as well as the technologies for producing it, treatment techniques, pharma-informatics systems, and ingestible event marker systems, were all patentable as a consequence of the patent research.

The information gathered for this research shows the potential and demand in the worldwide pharmaceutical market for digital pills with ingestible sensors.

13. CONCLUSION

The analysis of the patent landscape reveals a significant increase in patents related to digital pills with ingestible sensors, highlighting rapid and active development in the field of digital medicine technologies. The top 20 most innovative applications are focused on advancements in endoscopic diagnostics, smart drug delivery, and mobile clinical monitoring.

However, several issues must be addressed to achieve the quick adoption of digital pills into medical practice. These include technical constraints, medical ethics, legal frameworks, and extensive clinical trials to ensure safety and efficacy. More research and development into scientific and practical methods for implementing safe and effective digital pills are likely to lead to better treatment outcomes, higher compliance, shorter hospital stays, mobile clinical monitoring, lower treatment costs, and a more mainstream presence for healthcare companies.

The current revolution in healthcare driven by digital health technologies promises significant improvements in patient care, streamlining healthcare delivery, and opening new directions for medical research. Innovations such as smart medications, wearable technology, telehealth, and artificial intelligence have the potential to transform healthcare. However, realizing the full potential of these advancements critically depends on addressing patient privacy concerns, closing the digital divide, obtaining informed consent, and eliminating algorithmic bias.

Overcoming the ethical and practical challenges of digital health requires cooperation between technology developers, medical practitioners, legislators, and patients. By viewing these challenges as opportunities for growth and progress, we can steer the future of healthcare towards a scenario where digital health solutions are equitable, accessible, and essential for creating a better-informed and healthier population.

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