Digital Pills with Ingestible Sensors: Patent Landscape Analysis

Olena Litvinova [1,2], Elisabeth Klager [2], Nikolay T. Tzvetkov [3], Oliver Kimberger [2,4], Maria Kletecka-Pulker [2,5], Harald Willschke [2,4], Atanas G. Atanasov [2,6]

[1] National University of Pharmacy of the Ministry of Health of Ukraine, Kharkiv, Ukraine;
[2] Ludwig Boltzmann Institute Digital Health and Patient Safety, Medical University of Vienna, Vienna, Austria;
[3] Institute of Molecular Biology "Roumen Tsanev", Department of Biochemical Pharmacology and Drug Design, Bulgarian Academy of Sciences, Sofia, Bulgaria;
[4] Department of Anaesthesia, Intensive Care Medicine and Pain Medicine, Medical University of Vienna, Vienna, Austria;
[5] Institute for Ethics and Law in Medicine, University of Vienna, Vienna, Austria;
[6] Institute of Genetics and Animal Biotechnology of the Polish Academy of Sciences, Jastrzebiec, Poland

Background and Purpose:

According to the WHO global strategy, digital technologies are connected to the future of world health [1]. Digital pills occupy an important place among the digital health solutions. Digital pills contain integrated sensors that allow monitoring of the course of pharmacotherapy through an interaction with the software of, e.g., tablets and smartphones. Such monitoring is of great importance, as low patient compliance is a major challenge for all areas of medicine.

Digital pills have a significant potential for savings in healthcare costs by reducing the need for emergency medical care and hospitalization of patients. The annual costs of non-compliance range from US $100 billion up to US $290 billion in the US, €1.25 billion in Europe, and approximately US $7 billion in Australia [2].

Digital pills development is done by high-tech industries that are evolving rapidly and require innovation from manufacturers. One of the sources of information reflecting the innovation process is the patent documentation.

The purpose of this project was to analyze the patent landscape and systematize the main trends in the patent protection of digital pills with ingestible sensors worldwide, as well as to identify the patenting leaders and future perspectives in the field.

Materials and Methods

Up until July 2022, studies were conducted using an Internet database, such as the European Patent Office, the United States Patent Office, the United States Food and Drug Administration (FDA, Orange Book), the Lens database, Google Scholar, and ClinicalTrials.gov. The patent search results using the keywords ingestible sensor, digital pill, smart pill, and their combinations revealed 3101 patents and 1655 simple families. Then 3101 patents were analyzed using the International Patent Classification and Cooperative Patent Classification codes. Their codes used in the search are shown in table 1. As a result, the study covered 291 patents, including 132 families.

Table 1. The International Patent Classification and Cooperative Patent Classification codes are used in the patent search.

Code	Meaning
International Patent Classification	
A61B5/00	Measuring for diagnostic purposes radiation diagnosis diagnosis by ultrasonic, sonic or infrasonic waves Identification of persons
A61B5/07	Endoradiosondes
A61B5/145	Measuring characteristics of blood in vivo , e.g. gas concentration, pH-value measuring of blood pressure or blood flow non-radiation detecting or locating of foreign bodies in blood
A61K9/00	Medicinal preparations characterised by special physical form
Cooperative Patent Classification	
A61B5/073	Intestinal transmitters

Results and discussion

The patent landscape analysis shows an increase in the number of patents related to digital pills (Figure 1).

The leaders in the number of patents granted are the United States, the European Patent Office, Canada, Australia, and China, which account for 72% of the total number of patents in the world. It should be noted that some of the patents are no longer valid. Given the active development and replacement of technologies with newer, more modern ones, the patents are rarely kept in force for the maximum of 20 years (25 years for medicines).

Figure 2 shows the principal owners of patents in the field of digital pills with an ingestible sensor. Their inventions are in the fields of mobile clinical monitoring, targeted drug delivery, and endoscopy diagnostics.

Proteus Digital Health (USA) is one of the leading companies creating ingestible sensor systems. “Ingestible Event Marker”—made by Proteus Digital Health was used to create the drug Abilify MyCite by Otsuka Pharmaceutical Company (Tokyo, Japan), received the FDA’s first approval of a digital medicine system in 2017.

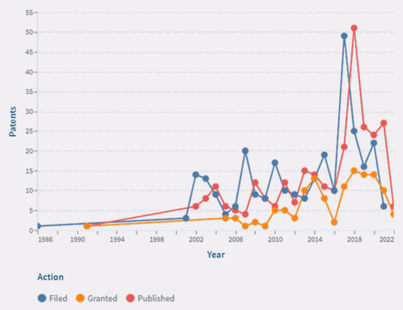


Figure 1. Dynamics of patent activity by applicants in the field of digital pills with ingestible sensor

Figure 2. Top owners of patents in the field of digital pills with ingestible sensors

The four components of Abilify MyCite interact using Bluetooth technology: the medicine, which contains the active ingredient aripiprazole; a sensor that transmits a signal to a patch worn on the patient; a smartphone app; and an online portal. The 1-mm-sized sensor is built into the tablet. It is made of cuprous chloride (copper), magnesium, and silicon and releases a signal to the patch when it encounters stomach acid. This information is then transmitted to the smartphone app.

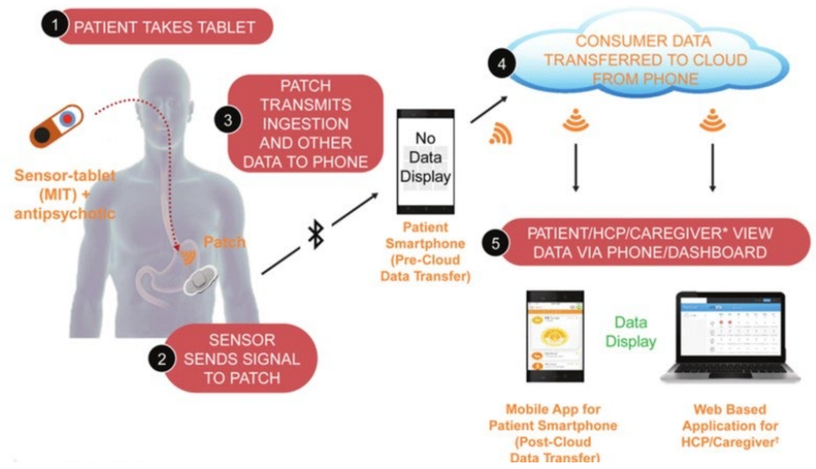


Figure 3. Digital medicine system: Abilify MyCite . Reprinted from ref [3].

The analysis established powerful patent protection of Abilify MyCite. It is protected by 32 US patents. This digital pill has six hundred and seventy-one patent family members in forty-one countries.

The analysis of the patent landscape made it possible to identify the main therapeutic areas in which digital pills with ingestible sensors have proved themselves to be applicable.

Diseases of the nervous system.
Abilify MyCite= Aripiprazole + Ingestible Event Marker (Proteus Digital Health, Inc. USA; Otsuka Pharmaceutical Co., Japan)

HIV/AIDS.
Antiretroviral therapy + Ingestible Event Marker (Proteus Digital Health, Inc. USA)
Antiretroviral therapy + ID-CapTM System (etectRx, USA)

Pain control.
Cyclooxygenase-2 Selective NSAIDs + digital pill = US2021244672 (Tremeau Pharmaceuticals Inc., USA)
Opioid antidote + digital capsule = CA3149412 (Celero Systems, USA)
Oxycodone/acetaminophen+Ingestible Event Marker (Proteus Digital Health, Inc. USA)

Cardiovascular diseases.
Lisinopril + Ingestible Event Marker (Proteus Digital Health, Inc. USA)

Diabetes.
2 antihypertensives and metformin and/or a sulfonylurea + Ingestible Event Marker (Proteus Digital Health, Inc. US)
Insulin targeted drug delivery = CA2840617 (Rani Therapeutics LLC, USA)

Gastroenterology
Immunosuppressant (Cyclosporine, Tacrolimus) targeted drug delivery = WO 2018/112255A1 (Progenity, Inc., USA)
Velpatasvir and sofosbuvir + Ingestible Event Marker (Proteus Digital Health, Inc. USA)

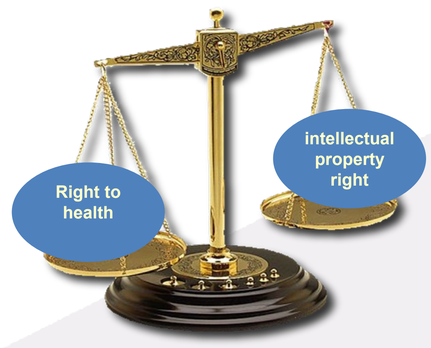
Oncology
Capecitabine Ingestible + Ingestible Event Marker (Proteus Digital Health, Inc. USA)

Tuberculosis.
Isoniazid and rifampin + Ingestible Event Marker (Proteus Digital Health, Inc. USA)

The above-described digital pill patents are presented for the purposes of illustration and not of limitation.

Conclusions

1. The patent landscape analysis shows an increase in the number of patents related to digital pills with ingestible sensors, which indicates the rapid progress and highly dynamic field of digital medicine technologies.
2. The following main areas of patenting digital pills with ingestible sensors have been identified: treatment in the areas of mental health, HIV/AIDS, pain control, cardiovascular diseases, diabetes, gastroenterology (including hepatitis C), oncology, tuberculosis, and transplantology.
3. Thus, the development of further scientific and practical approaches to the implementation of effective and safe digital pills will improve treatment outcomes, increase compliance, reduce hospital stays, provide mobile clinical monitoring, have a positive impact on treatment costs, and most likely become mainstream for most of the companies in the healthcare sector.
4. Further large-scale comparative randomized clinical trials evaluating the efficacy and safety of digital and non-digital forms and meta-analysis data are needed.



Referenzen

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