

EIP

Loonshot in Surgical Robotics - Patent Landscape Analysis

Loonshot = an idea that's not just big, it seems mad to even try - Safi Bahcall

Robot-assisted surgery is a hot area in Medtech. The number of patent filings in robotic surgery system (patent classification A61B/34) has been increasing drastically since 2015. Did you know that even Google was trying to get into the business? (search: verb surgical)

Background

Robotic surgery system was initially developed in the 1980s by Stanford Research Institute (SRI) International in California, USA, funded by Defense Advanced Research Projects Agency (DARPA) in the pursuit of saving lives on the battlefield while remotely operating on patients. The first manipulator invented and patented by SRI was a robotic system with haptic feedback, which includes a force sensing element mounted distal to the holder and the drive assembly for detecting forces exerted on the surgical instrument and providing feedback to the surgeon (CA2222150C, US6788999B).

NASA also funded SRI to develop a robotic surgery system that could provide medical assistance for astronauts during their remote mission at Mars or the Moon. However, they soon concluded this project because it appeared that controlling telesurgical robots in space is almost impossible due to the time delay caused by the great distances. During the same period, NASA also invented a wearable head-mounted display that allowed one to interact with and control images in a Virtual Reality (VR) environment. Coupled with VPL's DataGlove, this led to the realisation of telepresence robotic surgery.

Commercialisation of robotic surgery systems

Computer Motion

Computer Motion developed AESOP (Automated Endoscopic System for Optimal Positioning), which was the first surgical robot to receive FDA clearance in 1994. In collaboration with Stryker, they soon developed the first complete robotic surgery system called ZEUS, which received FDA approval in 2001. The ZEUS system was marketed at a price of USD\$975000 in 2003.

Intuitive Surgical

Around the same time in 1995, Intuitive Surgical was founded. After negotiating with SRI about their intellectual property, Intuitive Surgical built their first prototype called Leonardo by adding a wrist to the end of the patient-side instrument manipulator to create a sixth and seventh degrees of freedom. Animal trials were carried out in 1996 using the Leonardo prototype, which provided great insights into the development of the second prototype called Mona. Mona is equipped with an exchangeable instrumentation and it had proved success in human trials. Further improvements and the addition of a stand-alone cart housing patient-side operative components led to the birth of the da Vinci system. The da Vinci system received FDA approval in 2000, with a market price at around USD\$1m. By 2002, 60 da Vinci systems were sold with a total sale of USD\$72m[1].

Patent War

In 2000, Computer Motion filed lawsuits against Intuitive Surgical alleging patent infringement of 9 separate patents. In response, Intuitive Surgical filed Oppositions at European Patent Office against some of Computer Motions European patents. The patent disputes lasted for about three years until the two companies merged in 2003 to end the litigations, and also to combine the talent and energy of both companies in developing and growing the application of robotics to minimally invasive surgery. The ZEUS system was phased out in favour of da Vinci system.

da Vinci System

The da Vinci surgical system is used today by surgeons to deliver a less invasive approach to many types of surgery. The system comprises the following main components:

- Surgeon's Console: allows surgeons to operate while comfortably seated at an

ergonomic console viewing a 3DHD image of the surgical field.

- Patient-side Cart: holds electromechanical arms that manipulate the instruments inside the patient. Up to four arms attached to the cart can be positioned and locked into place, with a first arm representing the surgeon's left hand, a second arm representing the surgeon's right hand, a third arm positioning the endoscope, and a fourth arm enabling the surgeon to add a surgical instrument to perform additional tasks.
- 3DHD Vision System: includes an endoscope to provide 3DHD image that has high resolution, high contrast, low flicker and low cross-fading video images with zoom-in function.

Additional components include:

- Integrated Table Motion: this coordinates the movements of the robotic arms with an advanced operating room table to enable management of the patient's position in real time while the robotic arms remain docked.
- Firefly Fluorescence Imaging, which combines a fluorescent dye with a specialised camera head and laser-based illuminator to allow surgeons to identify vasculature, tissue perfusion or biliary ducts in 3D beneath tissue surfaces to visualise critical anatomy.

Today, more than 10M procedures had been performed worldwide using the da Vinci systems, with about 6730 systems installed around the world[2]. Intuitive Surgical has been dominating the market (about 80% of the market share according to BIS research[3]) since early 2000s thanks to its strong patent protection strategy. The company has been increasing their patent filings since early to mid-2000s, currently with a patent portfolio consisting of about 1026 patent families. The latest fourth generation for example, the da Vinci Xi system, is protected by at least 68 patent families[4].

Since patent has a lifetime of 20 years, some of the fundamental patents Intuitive Surgical filed in late 1990s have expired in recent years, and many new players seized the opportunity and entered the market.

Current Robotic Surgery Systems Landscape

The graph at the beginning of the article shows the current robotic surgery systems patent landscape. The result may be surprising to some as it shows that Johnson & Johnson has topped the list as the company with the largest patent filings in the field of

robotic surgery systems, partly due to its aggressive M&A activities in recent years. Having said that, J&J's robotic surgery system Ottava is expecting a delay due to technical development challenges and supply chain disruptions caused by covid-19, pushing their first-in-human trials to the second half of 2024. In the meantime, Medtronic's robotic surgery system Hugo has recently received CE approval for gynecological and urological procedures in Europe, moving the company closer to rivaling with the market leader Intuitive Surgical.

While the filing activity gives us a glimpse into the market landscape, it nevertheless says nothing about the quality or significance of its patents. One way to evaluate the quality or significance of patent is by looking at the number of citations – how many times the patent has been cited as prior art by another patent, usually during examinations. The table below shows the number of patent documents that have been cited by company.

Forward citation frequency by 1st assignee

1. Assignee/applicant (first): Johnson & Johnson. Document: 3685
2. Assignee/applicant (first): Intuitive Surgical Inc. Document: 2806
3. Assignee/applicant (first): Metronic Inc. Document: 2118
4. Assignee/applicant (first): Koninklijke Philips NV. Document: 1030
5. Assignee/applicant (first): Stryker Corp. Document: 790
6. Assignee/applicant (first): Siemens Healthineers. Document: 582
7. Assignee/applicant (first): Olympus Corp. Document: 539
8. Assignee/applicant (first): CMR Surgical Ltd. Document: 382
9. Assignee/applicant (first): Brainlab AG. Document: 362
10. Assignee/applicant (first): Globus Medical Inc. Document: 340
11. Assignee/applicant (first): Sony Corp. Document: 288

Unsurprisingly, the list largely follows the above graphs. But it is interesting to see Brainlab going on the list at number 9, which positively indicates the quality of its patent portfolio compared to other companies in the field. Sony Corp may be a surprising catch for a lot of people since it is not a medical device company as such, but their R&D centre has been doing research on robotics technology and found its application in surgical robots.

THREE reasons MedTech

game in filing patents for robotic surgery systems

Ample unexplored 'white spaces'

Similar to how the one-click check out patent helped Amazon to dominate the market, Intuitive Surgical is able to stand as a leader in the field of medical robotics because it is an early adopter of the robotics technology in surgery, and it had diligently protected their technology.

Fortunately, medical robotics is still a relatively new niche. There is a need for innovation and growth, and there are still a lot of 'white spaces' – gaps in the patent landscape that can drive the development of new inventions. Companies can look internally for areas where they have existing ability to drive innovation which they can capitalise on, and a patent landscape search can assist them to navigate the 'white spaces' in the medical robotics field. There is nothing worse than doing the wrong thing well, especially when innovations in MedTech usually involve a huge amount of capital.

Useful tool to expand market share

The global medical robotics market size is estimated to grow from US\$6.1bn in 2020 to US\$22.27bn by 2028, growing at a CAGR of 17.6% during this period[5]. Main drivers include the rising demand for minimally invasive surgeries (MIS) thanks to the advantages associated with these procedures such as faster recovery periods and increased safety for the patients, better visualisation capabilities for the surgeons, growing incidences of chronic diseases worldwide as well as growing elderly population. Emerging markets such as India, Brazil and China are expected to offer significant opportunities for players in the medical robotics field due to fast rising adoption of robotics in surgery.

Since patents are based on a first-to-file system, timing is key. Companies should have an invention harvesting system in place to proactively turn aspiration into action. Building a sound patent portfolio is a strong tool to block competitors and it enables the company to have a competitive edge.

New stream of income

Field-of-use licensing can create a new stream of income for the company. Robotics is a hot area – not only is it applied in surgery, but also for example in manufacturing, and

packaging. Patents directing to a general robotic system to be used in a medical procedure but that could also be used in other fields could potentially be licensed out to companies in a non-competing industry. For example, US10117713B owned by Stryker, its independent claim 1 directs to a method for controlling a manipulator and a tool coupled to the manipulator to remove material from a workpiece during a procedure with a robotic system including a navigation computer and a manipulator controller coupled to the manipulator. Patents can, therefore, not only be a defensive strategy to block competitors, but also an income-generating asset by collecting royalties from licensing to companies in non-competing industry.

Conclusion

With the advent of 5G, it would be exciting to see robotic telesurgery to be performed in space one day soon. It is hoped that competition will drive research and innovation further and lower the price of the systems to make minimally invasive and keyholes surgeries more accessible to patients with new players coming into the market. It is estimated that the market for robotic-assisted surgical procedure is less than 2% penetrated globally (5% in the US)[6], indicating that there are still plenty of opportunities. Patent data is useful in providing us a bird-eye view of the current market landscape, but it is equally useful in identifying 'white space' for companies looking to establish themselves in the field.

[1]Intuitive Surgical and Computer Motion Announce Merger Agreement | Intuitive Surgical

[2]Intuitive | Robotic Assisted Surgical Company | About Us

[3]Global Surgical Robotics Market - Analysis (2017-2025)| BIS Research

[4]Intuitive | Robotic Surgical Company | Legal | Patent Notice

[5]Surgical Robots Market size worth \$ 22.27 Billion, Globally, by 2028 at 17.60% CAGR: Verified Market Research® (prnewswire.com)

[6] Medtronic plc (MDT) Management Presents at 13th Annual Well Fargo Securities Healthcare Brokers Conference, 6 Sept 2018

Medtronic plc (MDT) Management Presents at 13th Annual Wells Fargo Securities Healthcare Brokers Conference (Transcript) | Seeking Alpha