Industry Case Study Series on IP-Management

B. Braun
Medicine 4.0 and respiratory gas analysis

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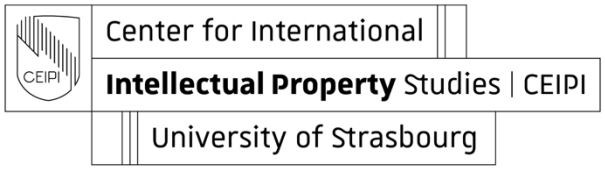

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Dr. Maier is Senior Vice President Innovation & IP-Management Divisions Hospital Care and Out Patient Market at B. Braun Melsungen AG - one of the world´s leading healthcare suppliers. In his 40 years career in the medical and pharma industry he gained comprehensive experiences not only in the development of medical devices and pharmaceutical products but also in marketing as well as in production. With this knowledge, he and his team has the goal to strengthen the innovation leadership of B. Braun in the mentioned fields.

Another area of responsibility is the management of the company Nutrichem diät + pharma GmbH. This firm develops and produces enteral nutrition, nutritional supplements and sports nutrition.

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Solvej Fritsche

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PART I

The healthcare market

The global healthcare market is growing by 6% per annum. An increasing number of people spend increasing amounts of money on their health. Population growth and rising per capita spending mean that the healthcare industry is developing faster than other sectors. The steady development of the key drivers of this growth is going to continue: GDP and purchasing power, ageing, and technological progress. The global market volume is expected to reach USD 20 trillion by 2030.

The disease profile around the world is changing. Fortunately, poverty-related diseases and deaths are on the decline, while chronic and age-related diseases such as cardiovascular conditions are on the increase. Prosperity-related diseases such as diabetes are also on the rise: the World Health Organization (WHO) estimates that the number of cases of diabetes mellitus type II will increase by 39% and the number of deaths caused by it will have risen by about 70% by 2030. Another prominent example is dementia: the WHO predicts a 140% increase in occurrence by 2030. A large proportion of these patients will be in need of full-time care.

Technical progress in terms of process improvements, newly discovered drugs, biotechnological active ingredients, diagnostics and medtech processes leads to contrasting effects: on the one hand, it enables us to cure previously incurable diseases (e.g. some forms of cancer). These desirable effects lead to additional treatment costs and generally also to an extended use of the healthcare system. On the other hand, there are learning curves like in any other industry: shorter occupancy of hospital beds, process cost savings due to e-health and discovery of new treatment methods. The bottom line is that costs are rising due to technical progress, because the additional treatment costs outweigh the benefits gained from efficiency improvements. Especially in the wealthy countries, technological progress in the medical sector continues to be one of the main reasons why healthcare markets grow faster than GDP. This is indicative of a social preference, because societies have always chosen to devote a large proportion of their wealth to prolonging and improving life in the past.

The healthcare industry plays an important role in German foreign trade. With exports worth almost EUR 80 billion and a trade surplus of EUR 15 billion, it contributes to the positive trade balance of the German economy. After automotive, machinery, chemicals, and electrical and optical products, the healthcare industry is the fifth largest export sector. Exports increase by over 5% per annum. Some 70% of exported products and services of the healthcare sector are pharmaceuticals and medical technology. Medtech companies export to countries around the globe. The largest buyers are France, Russia and the Netherlands. What is striking is the fact that the USA account for more than 50% of the remaining exports outside Europe. In many markets, German medtech companies enjoy an excellent reputation. In the United

States, the majority of imported medical technology comes from Germany. The same is true for Saudi Arabia, Russia, and Poland. In Brazil, India, China, Argentina, Australia, South Africa, and Turkey, Germany is the second biggest supplier of medical technology.

Medical technology

The market for medical technology is a global growth market in which innovation advances at a rapid pace. Due to the sharp increase in competitive and cost-related pressure, stricter regulatory requirements, and the new challenges posed by digitization, the industry is currently undergoing fundamental transformation in Germany and Europe.

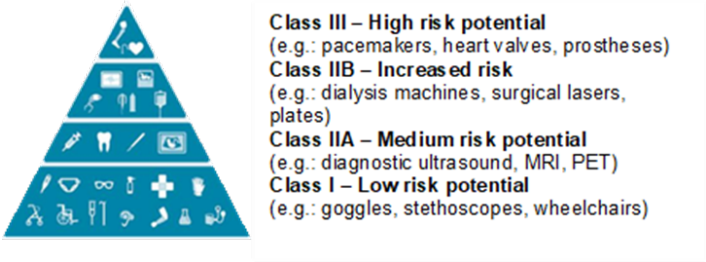
According to the German Medical Devices Act (MPG), medical devices include all instruments, appliances, devices, substances, and preparations consisting of materials or other objects, whether used individually or in combination, including software specifically intended by the manufacturer to be used for diagnostic or therapeutic purposes and software required for the proper functioning of a medical device to be used in human beings for the following purposes:

- Detection, prevention, monitoring, treatment, or relief of diseases
- Detection, monitoring, treatment, relief, or compensation of injuries or disabilities
- Examination, replacement, or modification of the anatomical structure or a physiological process

Medical devices are used in various areas of application:

- Hospital technology (e.g.: surgical robots, emergency stop buttons)
- Medical devices (e.g.: pacemakers, tooth implants)
- Diagnostic imaging (e.g.: sonography, x-ray)
- Tissue engineering (e.g. artificial organs)
- Medical IT (e.g.: simulation of surgical interventions)

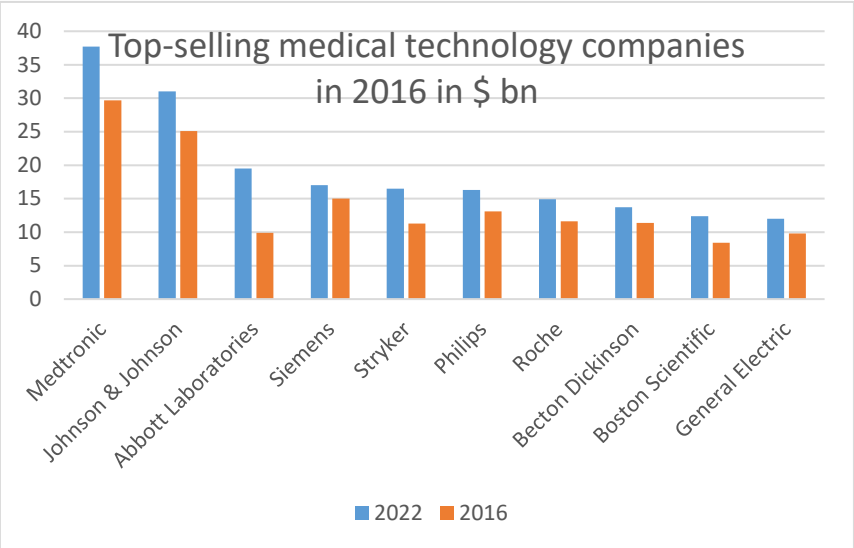
Medical devices are divided into different classes according to their risk potential for human health.

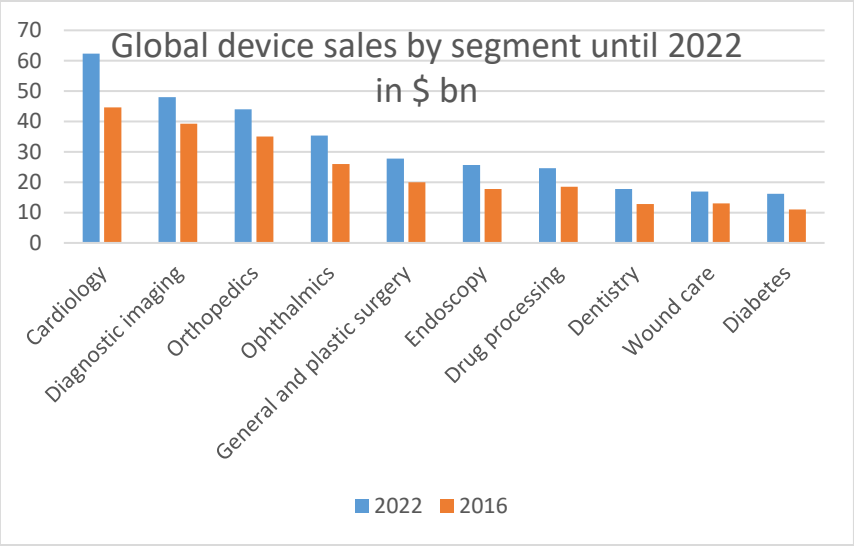


Source: Medtech Europe, image: BVMed

The global medtech markets are dominated by relatively few very large market players. The ten leading global players have a combined market share of 37% of total sales in the industry, while 95% of medtech companies are SMEs. In general, the market is highly globalized. In other words, German SMEs also compete with large corporations both at home and abroad.

The top performers in the industry are mainly companies from the U.S. The industry is characterized by a consistently high level of R&D efforts. Companies from other





North America is the leading market for medical technology, followed by Europe and Asia. Europe is home to about 25,000 medtech companies, half of which are based in Germany and most of which are SMEs. In Europe, some 650,000 people work for medtech companies, including about 210,000 jobs in Germany. The majority of European medtech companies are based in Germany, followed by the UK, Italy, Switzerland, Spain, and France. The average per capita expenditure on medical technology in Europe is approx. EUR 195 p.a., with the corresponding figure for North America being approx. EUR 380 p.a.

industry are entering the market and contributing their technological know-how and their development and production expertise to medical devices sector. The top-selling branches of the medtech industry are cardiology, imaging, and orthopedics.

Region	Market size	Market share
North America	204 bn €	45%
Europe	127 bn €	28%
Asia	88 bn €	19%
Rest of the world	37 bn €	8%
Germany	28 bn €	6%

So far, Asia has been the third largest market for medical technology after North America and Europe. However, it is the fastest-growing market. One of the main reasons for the rapid growth of the Asian market is the growing middle class in China. By 2025, the absolute size of the middle class is projected to reach about 600 million people. What is more, an increase in life expectancy among the Chinese population is causing a rise in demand for medical devices.

Important market trends include the ageing population around the globe and the growth

of the emerging markets. According to the U.S. Department of Health, the share of the world's population aged 60 and above will grow from 23% to 32% by 2050 in the industrialized countries. Considering that the age profile of industrialized countries is particularly high, the vast and fastest growing majority of people live in developing countries. The emerging markets will continue to shape the development of the medical technology sector for the next 50 years.

A key technology trend is "smart medical technology". Smart medical technology offers various benefits such as comprehensive 24/7/365 monitoring and care, personalized therapy, improved prevention, higher average life expectancy, lower treatment costs, etc. In order to be able to use digital ecosystems, metrological data analysis, and evolving value-added services, medical technology must be connected to the Internet of Things by means of cloud services. Currently, fitness apps and watches are still predominantly lifestyle products, but also show that a large proportion of consumers have long arrived in the e-health era. Medical technology is about validating the real-time data obtained and proving its clinical significance in such a way that it can find its way into prevention and therapy.

From a company perspective, it is important to take advantage of the opportunities arising from the digital revolution and to offer simple, user-friendly solutions to the patients of the future. At the same time, medical systems such as anesthesia devices, pacemakers, and magnetic resonance tomographs become susceptible to attacks when connected to the Internet. Security breaches of medical devices are extremely critical for data protection reasons alone. Therefore, manufacturers must ensure that users are effectively protected against unwanted third-party access when it comes to the cyber security of networked medical technology solutions.

Increasing regulation, increasing competition, and innovative technologies are bringing about complex challenges for the industry. For example, companies from outside the industry, such as automotive suppliers and software companies, are entering the medtech market with their technological know-how. Simultaneously, new market participants must comply with special structures and stringent requirements for certification and approval. Furthermore, the dual hospital financing system applies to capital goods. The reimbursement amount is also determined by contractual reimbursement prices. Companies from outside the industry often underestimate the particularities of national and international standards and regulations. Companies from the automotive sector, for example, have to prove that they have a special quality management system for medical technology in place. Software companies must classify some of their products as medical devices, which requires conformity assessments and CE marking.

The market for medtech products is very international. In other words, German SMEs also compete with large corporations both at

home and abroad. German SMEs often pursue a long-term corporate strategy combined with a high level of flexibility. The focus is mainly on high-margin niche segments.

- Differentiated premium segment: premium products that differ from competitive offers on the market and cover a special niche.
- Value segment: tailor-made solutions for customers at a lower price compared to the premium segment.

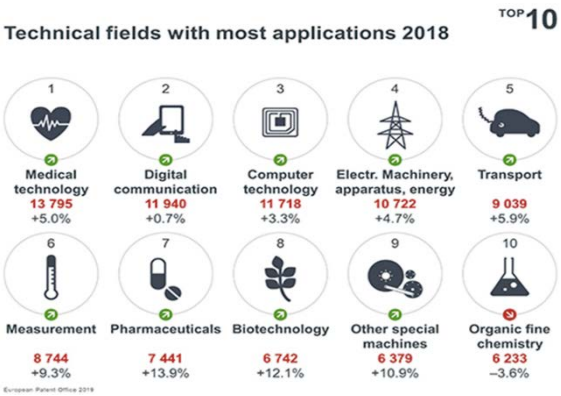
Ranking	Company	Members of staff	Turnover in $ bn
1	Fresenius Medical Care	90,690	16.74
2	Siemens Healthineers	45,000	12.93
3	Roche Diagnostics	88,509	9.99
4	B. Braun	54,017	6.13
5	Paul Hartmann	10,389	1.94
6	Drägerwerke	13,500	1.58
7	Karl Storz	7,100	1.28
8	Carl Zeiss Meditec	2,190	1.21
9	Otto Bock Healthcare	6,522	0.77

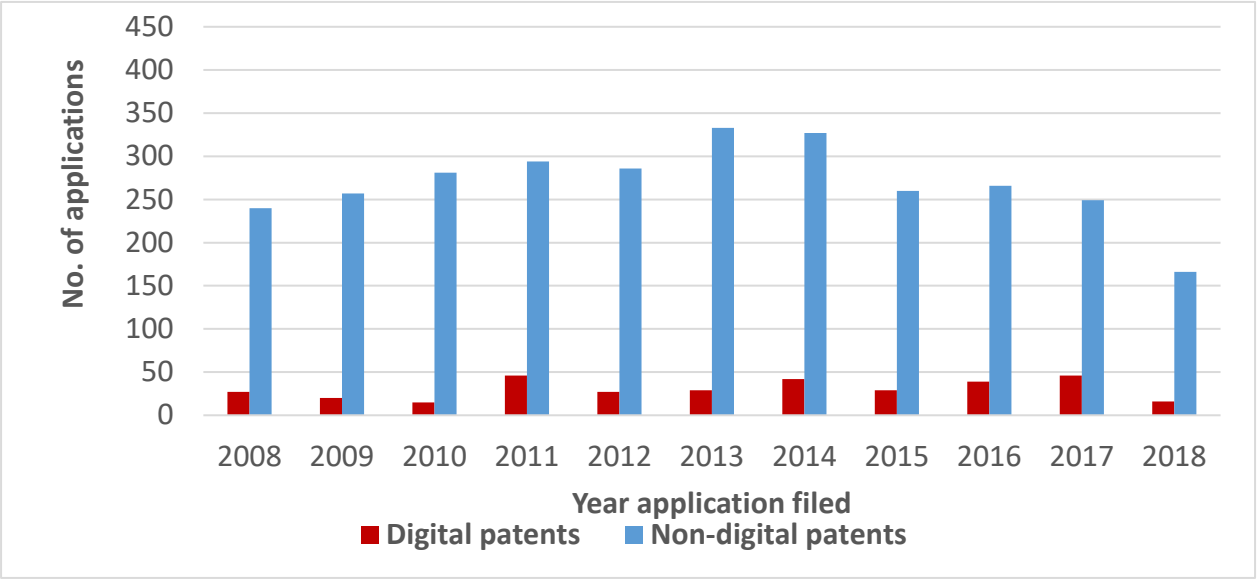
Market leaders in Germany (data from 2017)

Medical technology companies must deal with the following exogenous influences and position themselves accordingly:

- Digitization: Companies must align their business models with the digital age to remain successful in the long run. In doing so, they must comply with exigent data protection requirements for the use of sensitive personal health data.
- Cost pressure: The ongoing privatization of the hospital landscape, the bundling of demand in buying syndicates, the gradual implementation of DRGs (Diagnosis Related Groups): The classification system for a flat-rate billing procedure with which hospital cases are assigned to case groups on the basis of medical data in order to determine the billing amount and the increasing demands on benefit assessment as a prerequisite for reimbursement in the outpatient sector, are increasingly reducing gross margins.
- Regulatory requirements lead to more complexity, stringency and control
- Different regulations in connection with the approval and distribution of MedTech products in Europe, Asia, and the USA must be observed.
- Regulations have a direct impact on technological developments, the speed of innovation, market access, and the implementation of innovations in different markets.

Medical technology is a driver of innovation. The number of submitted patent applications illustrates the innovation efforts and dynamics of the medtech industry. With almost 13,800 patent applications, medical technology leads the list of technological fields at the European Patent Office. In Europe, with

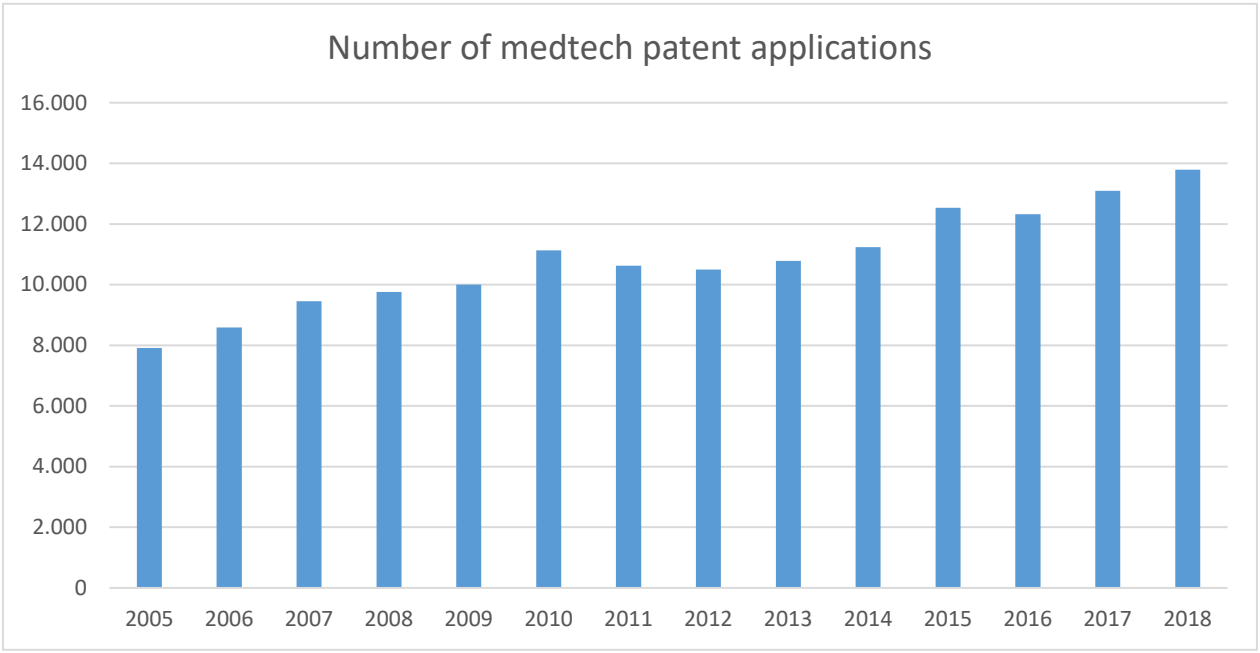


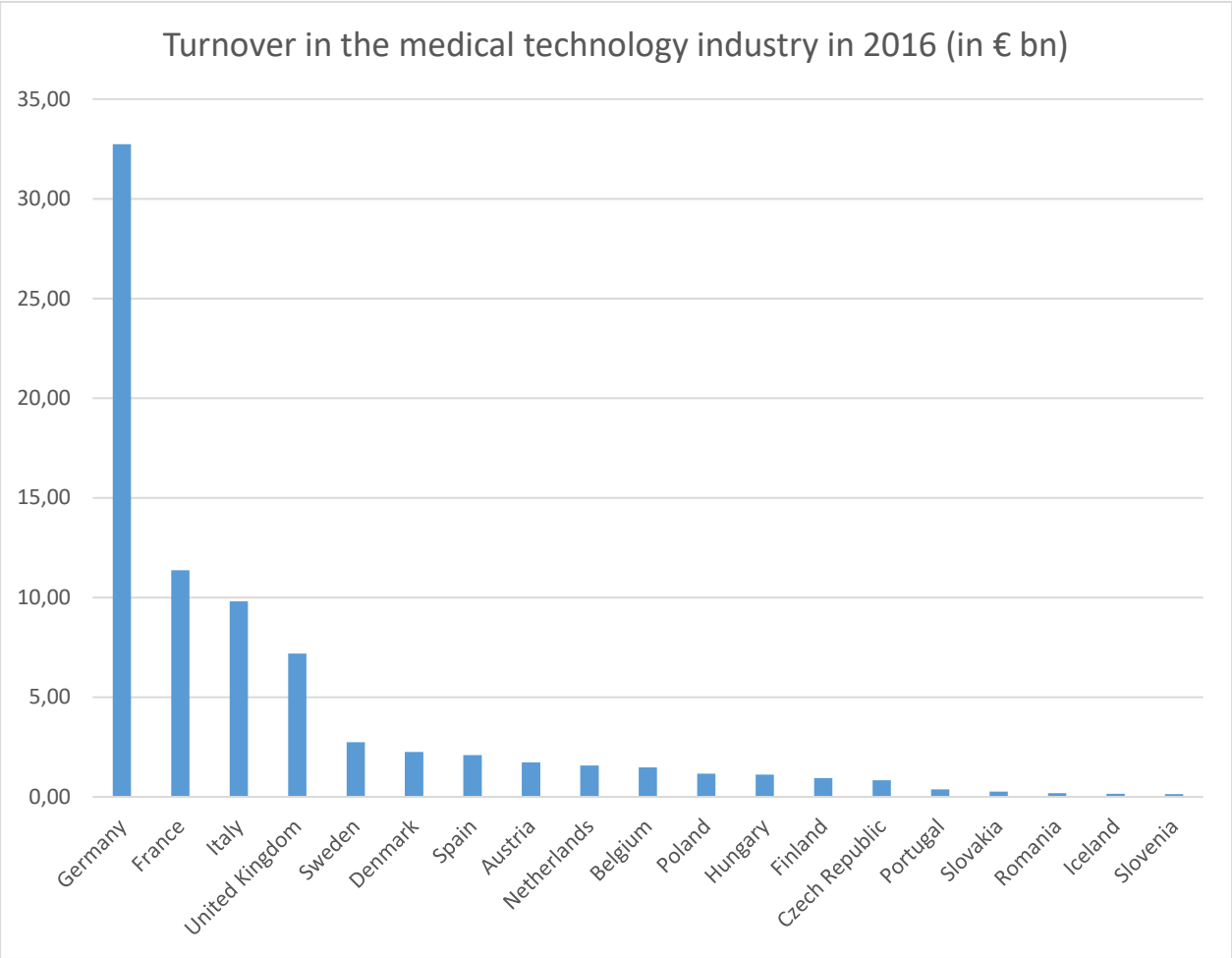


1,323 patent applications in this technological field, Germany has filed by far the most applications in Europe, followed by the Netherlands (868), Switzerland (598), France (492), and the United Kingdom (339).

The Dutch Philips group has filed the highest number of patent applications (761) in medical technology in Europe. Germany is by far the strongest market for medical technology in Europe, followed by Switzerland and France. Germany's market position and innovative strength are excellent. Technological product innovation in the field of medical technology can secure and even expand market shares.

As the number of European patent applications in the field of medical technology between 2005 and 2018 shows, there has been a high level of innovation in this technological field for many years.





The B. Braun company

B. Braun Melsungen AG is an international supplier to the healthcare sector providing products and services for hospitals, physicians in private practices, the home care sector, and extracorporeal blood treatment. The company employs some 64,000 members of staff in 64 countries, generates sales of almost EUR 7 billion (2018), and is owner-operated. The headquarters are in Melsungen, North Hesse, and the CEO is Anna Maria Braun.

The B. Braun company was founded by a pharmacy in Melsungen and acquired by Julius Wilhelm Braun in 1839. In 1864, his son, Bernhard Braun, started producing plasters and migraine sticks. In 1867, the pharmacy and the manufacture of pharmaceutical and medical products were spun off into two separate companies, and the latter was registered under its current name B. Braun. Today, B. Braun is one of the world's leading suppliers of solutions for the healthcare market, providing users and patients with products and product systems for anesthesia, intensive care, cardiology, extracorporeal blood treatment, and surgery. In total, the product portfolio comprises 5,000 products and 120,000 line items, 95 percent of which are manufactured in-house. Supplementary services and consulting offers make B. Braun

a system provider. With its products and services, the company contributes to optimizing workflows in hospitals and medical practices, and to improving safety for patients, doctors, and nursing staff.

B. Braun's business is subdivided into four divisions:

- Hospital Care equips hospitals and is a leader in clinical care and inpatient care products
- Aesculap is the global market leader for handheld surgical instruments
- Outpatient Market takes care of patient care outside of hospital operations, and of chronically ill or long-term patients
- B. Braun Avitum is one of three global full-service providers for extracorporeal blood treatment (dialysis)

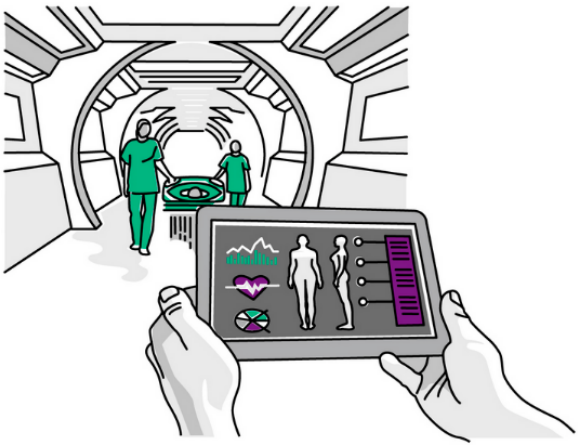
In 2017, brandeins business magazine and the Statista statistics platform voted B. Braun one of Germany's most innovative companies in the field of medical devices and products. B. Braun solves customers' problems in these fields by combining innovative products and services with intelligent processes.

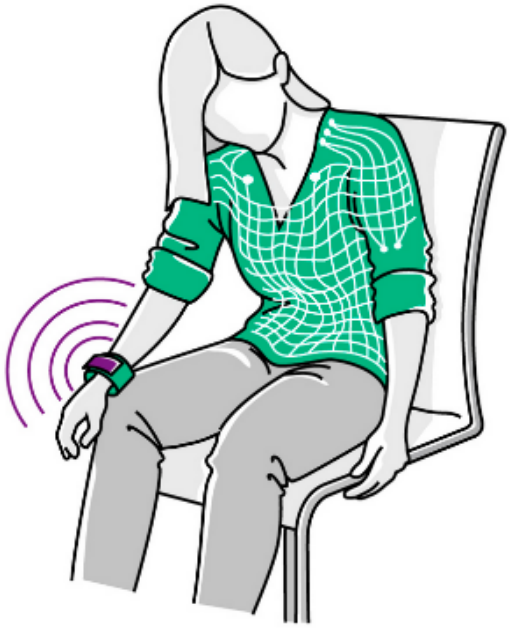
B. Braun is also part of the digital revolution in healthcare leading to Medicine 4.0. In addition to digitized products, which in turn are created in digital production networks, B. Braun also offers digital service solutions. In the age of digitization, innovations are developed faster than ever before, because with ever-increasing international competition, it is essential to constantly optimize products and services. The aims include improving clinical processes through digital solutions and providing customers with greater benefits at a lower cost. B. Braun has developed its own digitization strategy to position itself in the ever-changing digital medtech ecosystem. At B. Braun, digitization is not seen as a short-term trend, but as a process of continuous further development across all divisions. In this context, the company is also focusing on cultural change. Employees are learning to think in terms of end-to-end networking to an even greater extent. 80 percent of digital transformation consists of change management, the successes of which are becoming increasingly visible.

It is therefore not surprising that B. Braun has been awarded a large number of prizes. In 2017, the company received the "Digital Transformer of the Year" award, which is about the visibility of transformation successes. B. Braun came first ahead of BASF in the Life Sciences category. With its "werk_39" concept and the B. Braun Innovation Hub, the company also successfully manages the balancing act between structured daily business and an agile start-up atmosphere. The werk_39 innovation lab won the "Digital Lab Award" ahead of Merck, Boeing, and Volkswagen in 2019. The Innovation Lab is deliberately located outside the main plant of B. Braun's subsidiary, Aesculap, in Tuttlingen, Swabia, and was inaugurated in 2017. With a core team of ten, the laboratory specializes in developing digital solutions for clinical processes and new business models for customers beyond the actual product.

Medicine 4.0 in 2040

The following brief story illustrates how the customer journey for a fictitious patient called Karla is going to change over the next 20 years. Karla is 45, lives in a Central European city, is a non-smoker, works out and eats a flexigan diet, which is very common in urban environments in 2040. The flexigan diet is predominantly plant-based, but may occasionally include products of animal origin. However, stress continues to be a strong negative lifestyle factor in 2040 and many people still suffer from it. What is more, Karla has a genetic predisposition that increases her risk of cardiovascular disease. Karla has suddenly collapsed in the canteen while eating lunch, because she had a heart attack. But her colleagues do not call an ambulance. All they do is carefully put her in an upright position, because she is wearing a vest that takes care of initiating the necessary first aid procedures. The smart garment uses integrated sensors to measure ECG data, Karla's heart rate and skin conductivity, and uses a piece of software to establish Karla's health data, including prior conditions and genetic predispositions. The software detects





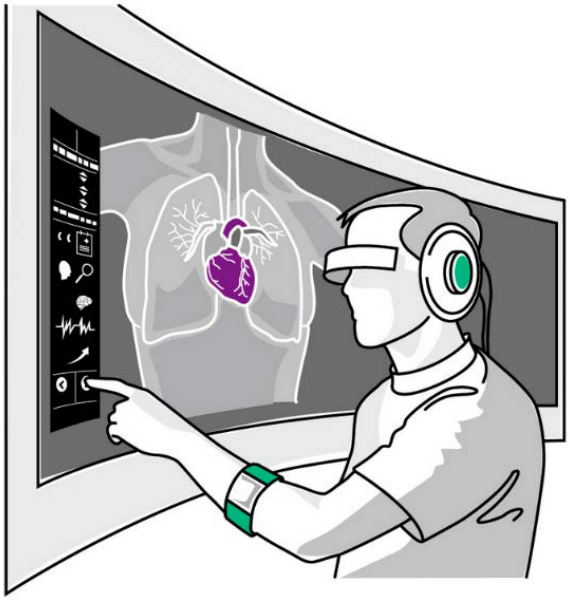
a critical situation – Karla's heart attack – and sends this information to Karla's smartwatch, which now flashes red like a traffic light and informs emergency services, who are already on their way to take Karla to the hospital.

The hospital of the future will look completely different due to extensive networking between hospitals, doctors, and individual hospital departments. The amount of available medical data, including blood counts, genetic data, experimental data, study data and smartphone app data has been growing exponentially and will continue to do so. Molecular medicine generated more data in 2015 alone than in the 15 years from 1990 to 2015. If this data can be circulated without privacy concerns and made available to physicians and nursing staff at all times in 2010, it will allow researchers and doctors to determine connections between health conditions and find potential cures, which in turn will lead

to a digital revolution in the healthcare sector.

Karla has arrived at the hospital. The doctors have already studied all the important information about Karla on their tablet or on their augmented reality goggles before she even arrives there. Filling in lists and forms is a thing of the past. Especially the comprehensive ECG analysis Karla's vest has performed over several months is extremely valuable now. Even continuous long-term data regarding the composition of her breath and providing information about Karla's metabolism is available, because it has been recorded by sensors in her bed while Karla was asleep. In 2040, patient files are no longer held by each individual healthcare provider, but are available at all times to all doctors in the form of digital patient records. In addition, doctors use special software and global databases where they can verify their diagnosis by matching them with other cases worldwide. But patients can help, too. The vest had warned Karla of a potential heart attack via her smartwatch two days ago, because the sensors had picked up irregularities in her ECG data. Karla did not see a doctor, because she was too busy at work and generally negligent.

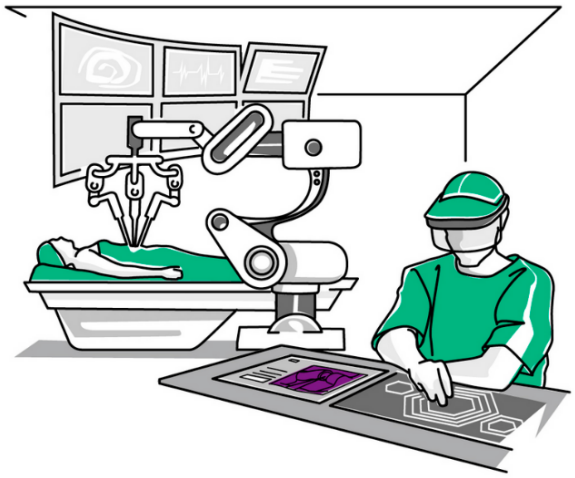
For Karla, the availability of comprehensive data means first and foremost that her diagnosis is significantly more substantiated than it used to be. What is more, she receives the right therapy faster, which has a major impact on her chances of recovery, especially when it comes to conditions such as heart attacks. And because Karla is instantly taken to the hospital, there is a very good chance that as much heart tissue as possible can be preserved and she will not suffer from chronic heart failure at a later stage.



The way hospitals are organized will also have undergone dramatic changes by 2040. Traditional hospitals often have a pavilion structure where departments are widely scattered, sometimes across separate small buildings on the hospital grounds. This is highly inefficient and causes critical points at which goods and people are concentrated. With the right planning, hospitals can prevent sources of error and save time. Within minutes of arriving at the emergency department, Karla is taken to the operating room without having to leave the building. The structural arrangement of the departments is compact, and everything that is connected within the same process is located within the same building.

Karla arrives at the operating room at break-neck speed. The operating theater looks surprisingly empty, because the OR of the future needs far fewer equipment. Large screens for MRI images or X-ray tubes are a thing of the past. In most cases, the surgeon and the patient are the only people in the room. The surgeon can zoom in on the patient and individual body parts using the integrated display of his smart goggles, and has all the important information on a single screen right in front of their eyes.

And because a piece of software has decoded and analyzed Karla's DNA many years ago, the doctors are able to select the best surgical method for her genetic setup. Before the procedure, Karla's surgeon checks the settings of the surgical robot. The surgeons of the future routinely use fully automated surgical robots for many clinical indications, creating a kind of teamwork routine between people and machines. The duration of surgical procedures is significantly reduced, and patients lose less blood and experience less post-surgical pain. Implants are made to measure using a 3D printer and include smart features such as the delivery of suitable medication.



For Karla, this means that her stent, which is placed with utmost precision and minimal blood loss by a surgical system, releases active ingredients and sends a message to the physician's smartphone in the event of complications.

Karla takes no notice of any of this. She is sedated and the depth of her anesthesia is continuously monitored via her breathing. Patients primarily notice the smartness of a smart hospital because there are fewer disruptions, shorter waiting times, fewer problems, and because the staff have more time to look after them in quieter surroundings. When Karla wakes up in her smart hospital bed, she can expect a much shorter idle time than before. The hospital bed is also equipped with respiratory gas analysis and continuously monitors various indicators in Karla's breath.

Karla is in pain, feels anxious and uncomfortable. She calls a nurse who immediately appears on a screen. A camera allows the nurse to see Karla. The nurse sees all of Karla's details on his tablet and can assess her precise

condition. He provides reassurance and controls drug delivery. He will be with Karla in person within just a few minutes and arranges a visit by the attending doctor.

Respiratory gas analysis – Edmon

Respiratory gas analysis has been used in medical diagnostics since ancient times. Even the ancient Greeks knew that diseases had a smell. Hippocrates paid attention to unpleasant smells as an indicator of possible health conditions. A sweet and fruity breath is an indicator for diabetes, for example, while an odor comparable to that of ammonia is indicative of a potential kidney problem, and a strong smell of decomposition is common in lung abscesses. The vision of respiratory gas analysis is a key foundation of Medicine 4.0.: data-based, non-invasive (in contrast to blood samples), always available online, and ideally embedded, i.e. virtually invisible or integrated with the environment. Breath tests and continuous breath monitoring could soon become everyday practice. angina pectoris, organ rejection, lung tumors, or sleep disorders will likely be identified by analyzing patients' breath going forward.

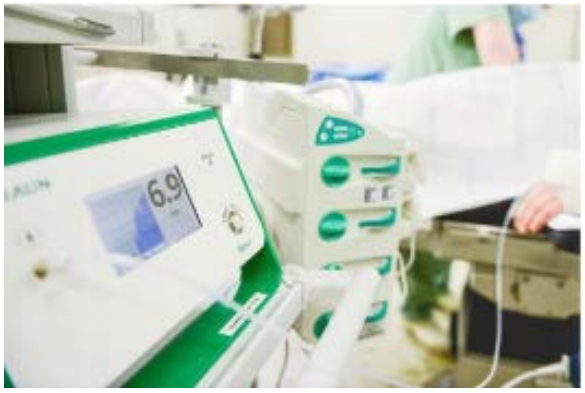
In the early 1970s, Nobel Prize winner Linus Pauling was the first to chemically examine human breath and discovered that the air we exhale consists of over 200 different gaseous substances. Numerous organic compounds (VOC, volatile organic compounds) can be detected and qualified in the exhaled air. The new occurrence of VOCs, changes in concentration, or abnormal patterns of several components appear to be characteristic of specific diseases. Rapid advances in technology enable the detection of tiniest traces of chemical compounds in the air we breathe. And these traces create a gaseous fingerprint determined by the distribution of volatile substances.

Gas chromatography coupled with mass spectrometry is the gold standard of respiratory gas analysis. However, these devices are unsuitable for mobile use as well as being cost-intensive and requiring extensive technical knowledge. For that reason, newer developments such as the "electronic nose" or ion mobility spectrometry (IMS) are used for bedside applications. The key advantage of these systems is that they enable a direct analysis at the patient's bed without having to prepare the sample first.

Compounds originating from the ambient air or from technical devices must be identified, as they do not belong to the patient's signature under investigation. In ventilated patients, the ventilation machine itself and the gas mixture used for ventilation can be a source of interfering substances. Depending

on the measuring method used, these background signals can make it difficult to identify the exhaled substances. Examples for the potential application of respiratory gas analysis include propofol (anesthetic) monitoring in the exhaled air, the impact of diseases relevant to intensive care, and data from animal testing.

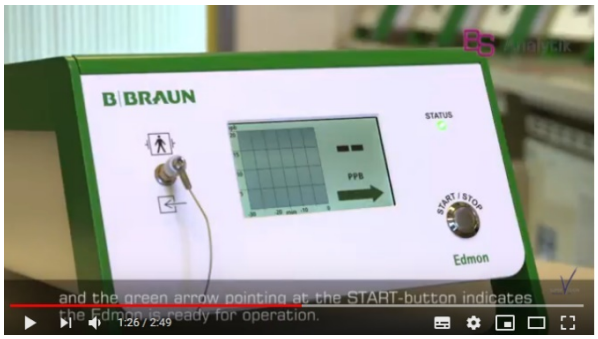
Drug monitoring by determining plasma levels of antibiotics and other substances has a firm place in intensive care. The main advantage of respiratory gas analysis is its non-invasiveness. What is more, blood test results only become available with considerable delays, are cost-intensive, and cannot be repeated an unlimited number of times. The number of drugs that have been detected in exhaled air is still relatively limited.



With sedation or general anesthesia, an online determination of the concentration of anesthetics in the breath is advantageous in order to avoid administering an overdose or underdose, and to ensure a quick and safe awakening of the patient, or to prevent the patient from waking up during surgery. In anesthesia, the measurement of the concentration of airborne volatile anesthetics in the breath is standard practice and was introduced to the clinical routine in the 1970s. However, the concentration is in the percentage range and can easily be detected using simple visual methods. With intravenously administered anesthetics, only propofol could so far be detected in exhaled air. However, exhaled propofol concentrations are in the trace range (ppb, parts per billion). This low concentration, the pronounced adhesive tendency of propofol, and the humidity of exhaled air pose particular challenges for the development of a precise measuring method.

The "Edmon" propofol monitor has been available as a medical device in Europe since 2017 to measure the concentration of propofol in the exhaled air of sedated or anesthetized patients. The measuring principle of the Edmon is based on ion mobility spectrometry and allows one reading per minute. In clinical studies, a very good correlation between propofol concentrations in exhaled air and in the plasma could be demonstrated in a pharmacokinetic model. For the first time, this enables the non-invasive monitoring of intravenous propofol application.

Clinical pictures in intensive care have a pronounced influence on metabolic processes, which are often reflected in changes in the exhaled air. Heart failure, for example, is diagnosed primarily based on the patient's clinical symptoms. In addition, the chemical analysis of the serum levels of "pro brain natriuretic peptide" (pro-BNP) in the laboratory can support the diagnosis.



https://youtu.be/YStjX2xE9sY

In patients with decompensated heart failure, however, elevated concentrations of the alkane pentane were also found in respiratory air. Furthermore, the concentration of volatile acetone correlated positively with the NYHA classification (New York Heart Association). Acutely decompensated patients could be differentiated from compensated heart failure patients with a precision similar to that of BNP determination. Patients with heart failure and increased acetone concentrations in the exhaled air showed an increased 1-year mortality and a greater probability of needing a heart transplant within one year.

https://youtu.be/0VpMWMysRlw

It is evident that different diseases can be diagnosed at an early stage by analyzing exhaled air. The main advantage lies in the ability to take non-invasive and continuous measurements, even over long periods of time, and thus to monitor them.

PART II

Active IP management at B. Braun

To address the various future fields of activity and challenges posed by digitization in IP management, B. Braun has developed an AIPM (active IP management) initiative, ready to be implemented. Intellectual property management is a collective term for strategic and operational activities, as well as management tasks that are part of the commercially oriented handling of intellectual property (IP). At B. Braun, IP management is understood as holistic and integrated management based on the systematic planning, management, and monitoring of intangible benefit potentials. The overall goal is to systematically build success by optimizing the appropriation of returns on innovation. The Edmon project, comprising a sampling system, a device, a system, processes, and workflows, was used as a pilot for the systematic development of a 360° IP strategy, which is ready to be subsequently implemented at B. Braun beyond Edmon.

The initiative focuses on three main areas: process adjustment, information management, and know-how. The strict regulatory requirements for medtech companies make the economic optimization of IP management a major challenge. The goals of the initiative included:

- Process adaptation: Detailed description of the process elements relevant for the design of the IP strategy; identification of the interfaces and integration of the IP process elements into the innovation process; structural inclusion in audit specifications
- Information management: Establishment of company-specific taxonomy structures; systematization and documentation of project-specific data such as exclusivity targets, customer benefits and relevant system components, provision and processing (incl. evaluation) of relevant patent information; permanent monitoring of the portfolio with regard to the achievement of strategic goals (controlling)
- Know-how development: Skills development; IP management as an integral part of the training plans of relevant employees; development of a seminar offer; integration into the company-wide e-learning concept; communication of the measures

The main task of the initiative is the integration of IP management as a creative part of the innovation process. To this end, IP is integrated into the innovation process at the earliest possible stage at which the question of the customer benefit to be provided and its constructive implementation can still be influenced. The goal is a two-way interaction between IP and innovation management for a successful market organization. IP management is understood as an integrated management system. Based on the existing technology and patent-driven processes, IP is integrated into other processes such as innovation, information, and marketing processes. The central IP process is essentially carried out by the company's own IP department, if

necessary in cooperation with external IP experts or patent attorneys, and with the inventor. The traditionally close link between patent work and the R&D department results in the occurrence of the phenomenon of 'operational islands' which are decoupled from the rest of the company. This effect can be overcome by integrating IP management with adjacent corporate functions. Integrated IP management is by default interdisciplinary. The systems of objectives and methods, in particular technology management, corporate and competitive strategy, marketing, and innovation management, are unified in IP management.

The overall goal of IP management is to systematically increase the company's success by optimizing the appropriation of economic returns from the company's innovation activities. In competitive differentiation, this means that an exclusive, enforceable, and sustainable customer benefit is required, which can be achieved with the help of IP.

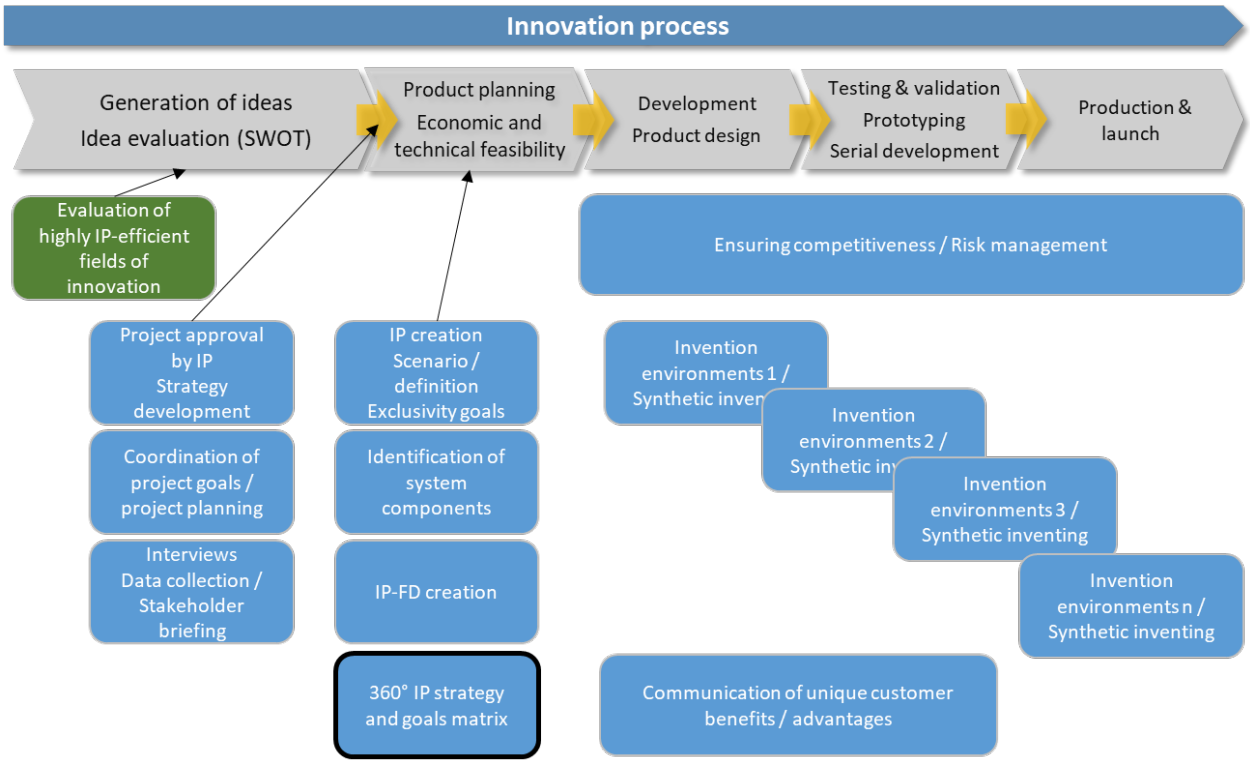
This general objective must be defined and specified more precisely within the framework of the Edmon IP strategy in order to ultimately arrive at a consistent package of measures which can be monitored and controlled in its operational implementation. As a central element of IP management, IP strategy – in keeping with Chandler's concept of strategy (1962) – defines the long-term goals with regard to the company's intellectual property, as well as the corresponding guidelines for pursuing these goals and the resources to be made available to that end. This includes in particular the identification of the IP required, which can be derived from the desired IP position needed in order to achieve the company's goals, plus the definition of the financial and human resources, as well as the organizational framework required for their implementation. IP strategy takes into account the various strategic options and derives from this the necessary measures for using IP as a means of actively and continuously developing the company's market position.

Process adaptation

Depending on its orientation, a company's IP strategy can either be primarily offensive or defensive in relation to its competitors. In practice, it is expedient to pursue hybrid strategies that include both defensive and offensive elements and are adapted on an ongoing basis. For a company the size of B. Braun with very different lines of business (see above), the basic orientation must be adjusted to reflect the company's competitive situation, position in the industrial value chain, customer structure, innovation cycles, etc.

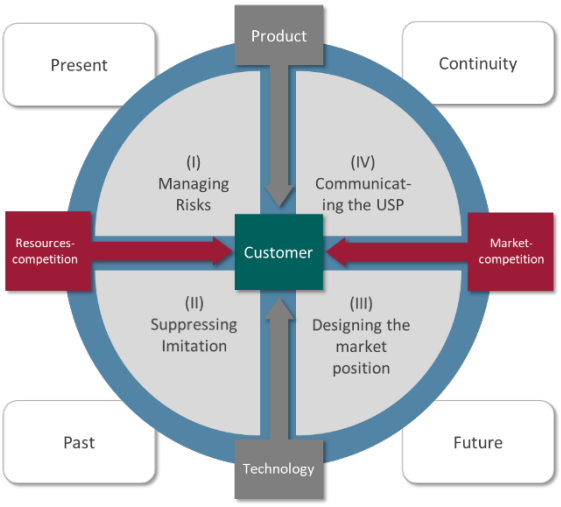
In order to create a sustainable sphere of exclusivity, IP management essentially has the following four areas of responsibility, which are both resource and market-oriented:

- Managing risks: The company must be able to identify and control all risks arising from IP – especially third-party IP – along its value chain at an early stage in order to gain the freedom of

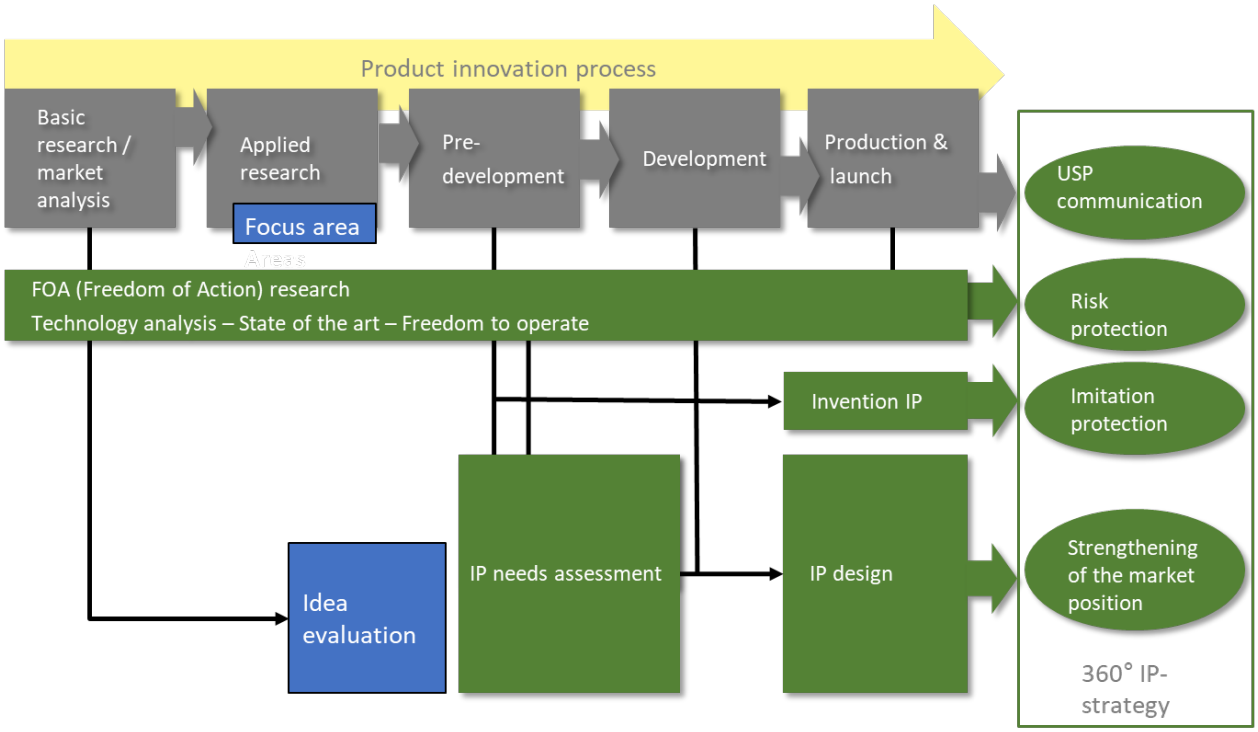


action needed to implement and safeguard its own business model in the long term.

- Suppressing imitation: Avoidance of imitation by making exclusive the company's own resources and core competencies which are necessary to create the most exclusive and superior offer position possible.
- Designing a unique market position: Securing own market access through strategic prohibition against the competition. Future products, services, and technology fields of the company, as well as the associated customer benefits, should be made exclusive for the company today. In doing so, the prohibitive effect associated with IP is purposefully used as a barrier to market entry, thus establishing an exclusive market position.
- Communicating the unique market position: Creation and maintenance of the differentiation potential and the unique position as perceived by the customer. The task of IP management is not only to objectively establish a unique position, but also to communicate this position to the customer.



The figure below shows the process and strategy perspective for the systematic development of a 360° IP strategy along an innovation process.



The task of IP management is not only to objectively establish a unique position, but also to communicate that position to the customer. To meet the objectives of IP management, the company must ensure the implementation of necessary and meaningful processes. The processes describe the essential challenges for IP management, while documenting tasks and goals, control criteria and resources, and the roles of the individual stakeholders.

The integration of IP management processes into the company's core processes is of crucial importance, both in terms of input and output factors, and in relation to the process owners, who, in the context of a company-wide IP management system, are not just part of the IP department.

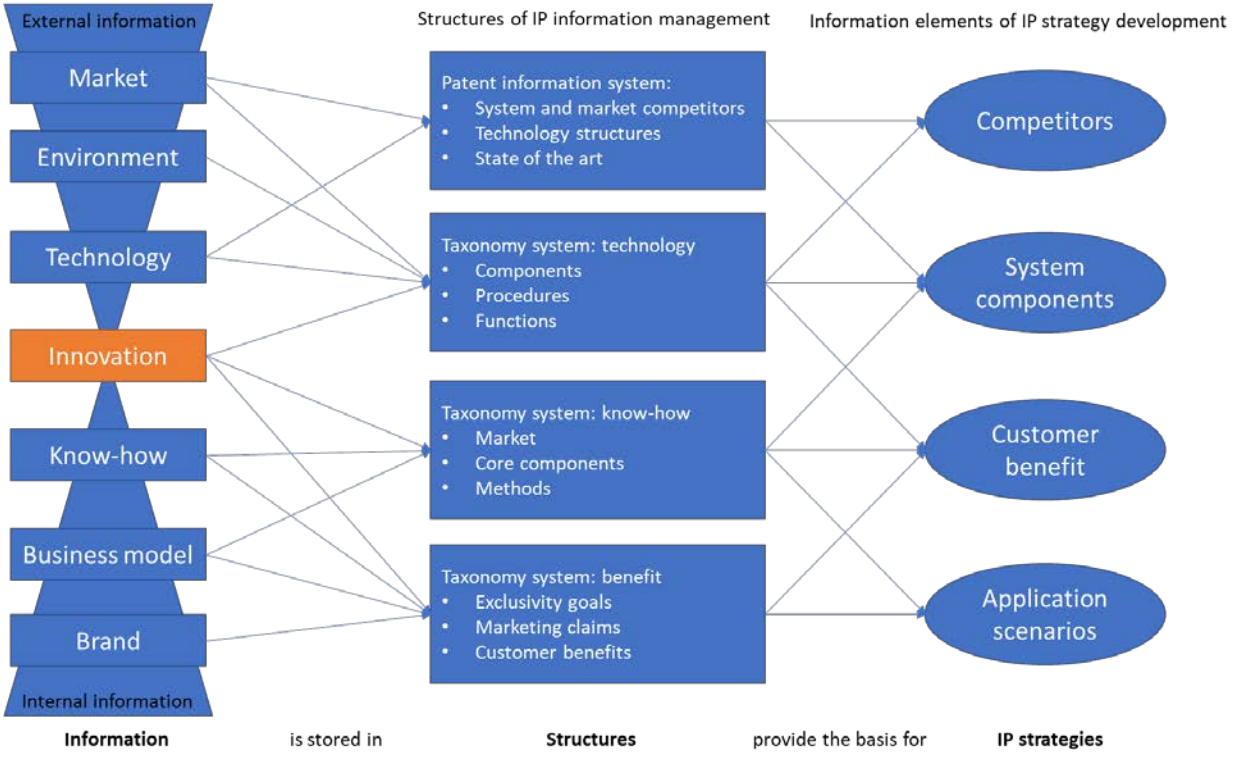
Pursuant to DIN 77006, IP management encompasses a process landscape that essentially consists of the following main processes:

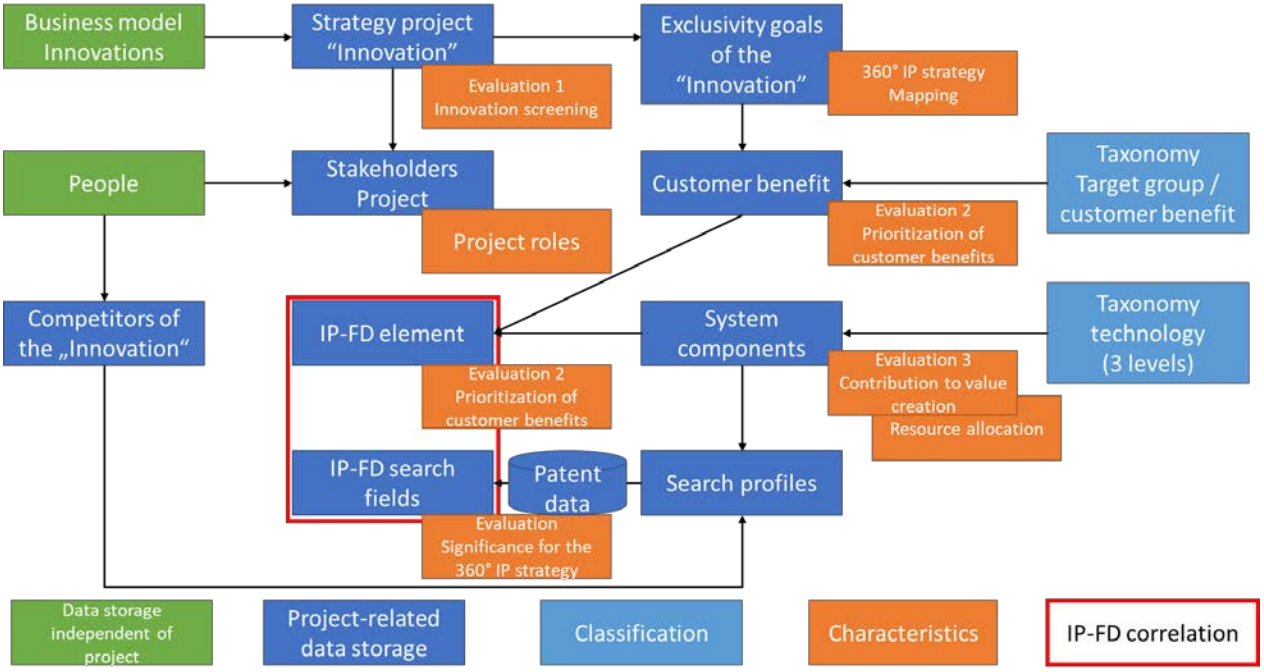
- IP strategy
- IP generation
- IP administration
- IP risk management
- IP enforcement
- IP defense
- IP transactions
- IP reporting
- IP awareness

Information management

Integrated information systems are of crucial infrastructural importance for IP management. The figure below shows the derivation of the four most important elements of IP strategy development from the analysis of the internal and external information at hand. The data is structured by developing several taxonomy systems. In other words, it is classified according to uniform categories which are suitable for the company or even the industry, and that allow the presentation, comparison, and further development of individual IP strategy projects using shared terminology. The effect of changes in the taxonomy, such as the addition of a new technology or a change in the customer's benefit perception, on the various projects can thus be captured and incorporated into a new opportunity/risk assessment. The regular review and adaptation of the taxonomy, as well as the monitoring and evaluation of the patent literature turn static IP strategy development projects into dynamic IP strategy development processes. If the information is structured and processed by such a system, and made available to all decision-makers at the point in time in the process when the necessary strategic decisions are made, then the IT-related prerequisites for strategic IP management are met.

A prerequisite for an efficient exchange of data and continuous updates of the IP information system is the decentralized responsibility for data maintenance, i.e. the transfer of responsibility to the data source. Information thus becomes a means of process integration and workflow design is geared to the requirements of the decision-making gateways. This enables a faster detection and



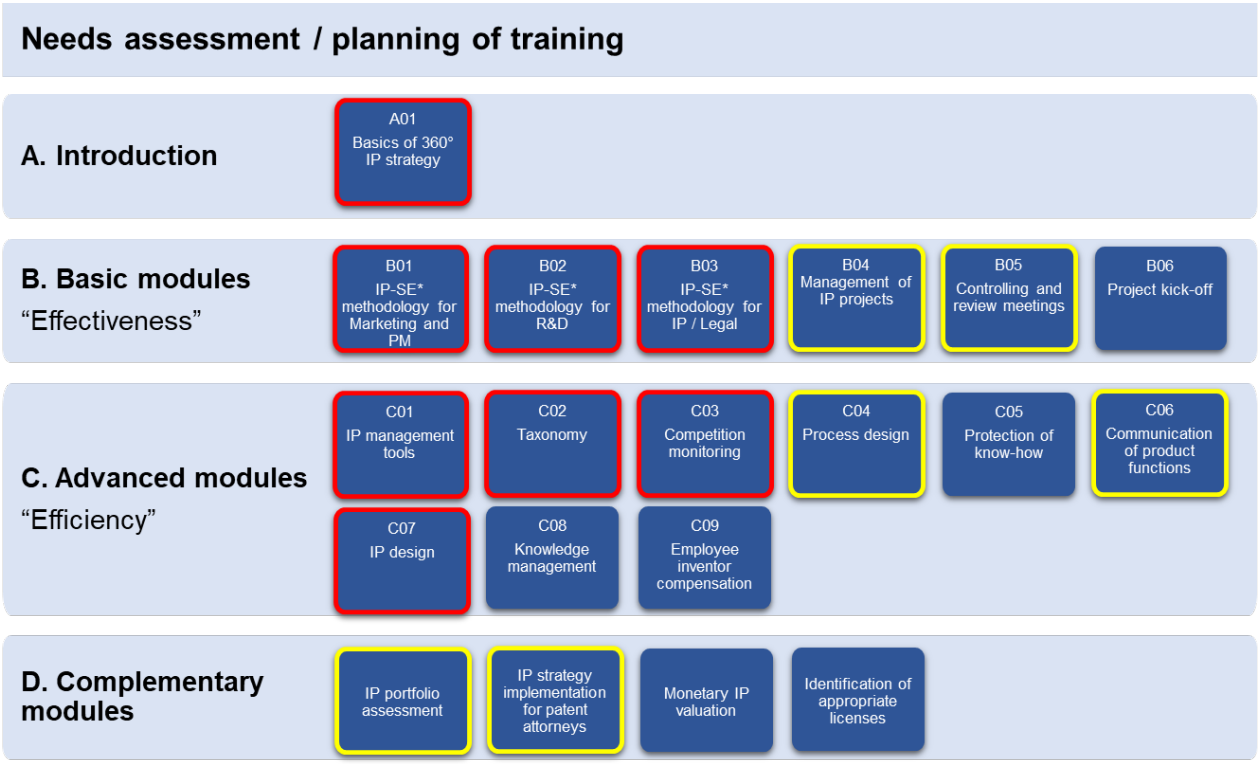


elimination of information deficits, and is the only way to ensure the quality of the decisions derived from such a system. The definition of processes, as well as the formal description of the structuring and processing of the information elements of IP strategy development in a reference model, enables an efficient implementation within the company.

The reference model serves as a model for the construction of company-specific models that reflect the individual circumstances of the enterprise. A simple data structure model, which is the basis for redesigning or adapting proprietary information structures to support the IP strategy development process, is set out in the figure above. This model meets the minimum data storage requirements from an IP perspective and provides interfaces to other company information systems via the information elements of innovation, competitors, customer benefits, and system components.

Know-how development

The developed IP management system, ready to be implemented, distinguishes between the tasks of IP experts from the patent or IP department, and the IP management functions that are assigned to the relevant employees in sales, marketing, product management, R&D, etc. These tasks primarily involve the identification of IP-relevant links with the aim of involving the relevant experts in good time and making decisions based on the IP-related information at hand. Suitable training courses shall ensure that the company's employees are equipped with the technical competences as well as the right motivation to use the new IP management system. The implementation will take place by means of a modular and flexible training



concept in which learning content is consolidated for specific target groups and project work is supported by coaching. On the one hand, this creates awareness of IP and the objectives of an IP strategy among employees who had previously not been familiar with IP from their training and work, as IP was not seen as a strategic marketing tool. On the other hand, members of technical staff with previous experience in dealing with IP from providing qualified input to the IP department in their role as inventors, need to be trained and educated in generating IP by means of synthetic inventing. But even the experts in the IP department need training in order to explain the new approach to IP and to show ways of aligning service and consulting tasks even more closely with the attainment of business objectives. Know-how development is essential when it comes to supporting and making sustainable change processes within the company.

In addition to developing technical skills, a key objective of training courses is to motivate employees in dealing with the challenges of IP management. As a result, a preliminary process and requirements analysis is an indispensable prerequisite for a customized and target group-specific training concept. The seminar content was initially developed on the basis of cross-industry case studies and allows employees to transfer the basics of IP strategy development to less complex internal implementation scenarios.

With the dissemination of the methodology throughout the company and growing empirical knowledge from real-life innovation projects, the seminars can then be tailored more closely to the company's specific needs.

As part of the transfer of IP management into the standard process organization, the experts from the IP department will then assume the role of coaches for the implementation of new IP strategy development projects, providing methods and tools, and acting as sparring partners for the familiarization with the new tasks. This allows individual employees or project teams to receive intensive support and to develop the necessary confidence in coping with the new tasks through direct feedback.

PART III

Summary: Success factors and benefits for B. Braun

B. Braun is confronted with the digital transformation of the healthcare ecosystem. In addition to high complexity, this ecosystem is also characterized by a vast number of regulatory requirements. These requirements deeply affect the processes of medtech companies, their products, innovation, and technology, including times to market. B. Braun stands out in terms of innovation competence by not just offering isolated products, but by understanding the sometimes highly complex processes of its customers, and offering holistic, integrative solutions and benefits. The AIPM initiative has strengthened B. Braun's ability to better capture and derive exclusivities from its actual innovation performance by means of IP, and to better support the increasingly digital approaches, including the user perspective.

Contact
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What is the MIPLM?

The 21st century marks a new era as our economies increasingly rely on knowledge-based production processes and services. Consequently, the institutions responsible for education and research in the field of intellectual property law in Europe must provide appropriate training for staff from the respective professional environments to acquire or reinforce their ability to initiate, control, protect, exploit and increase the value of intangible assets. The knowledge-based economy integrates research and development activities, innovation, industrialization and the marketing of products and services including intangible assets and completely revolutionizes enterprise management. It creates new professions specialized in dealing with intangible assets: this branch of law attracts consultants and intellectual property experts from among managers, jurists and lawyers. Indeed, every innovation process generated by new economic activities assumes the intervention of the law, the installation of tools and structures for developing or planning in order to control the intangible assets and to optimize their valorization. It has therefore been the duty of CEIPI, University of Strasbourg, as a leading center for Intellectual Property Studies in Europe, to propose a master program on "IP Law and Management" (MIPLM) since 2005, which complements the existing training course for engineers, scientists and lawyers. This "European" master program features a continuous training scheme aimed at experts in the field of intellectual property. It provides a genuine education program based on an investigation carried out in large enterprises in Europe. The teaching staff comprises academics and experts from various countries, renowned for their work and competence in dealing with the impact of intellectual property on the policy of enterprises.

M. Yann Basire
Director General of CEIPI

Intellectual property has become a crucial factor and driving force in the knowledge-based economy. The economic development and the competitiveness of companies increasingly depend on the generation and exploitation of knowledge. Intellectual property can convert investment in corporate knowledge creation into economic benefits. Thus IP-based appropriation strategies form the basis for creating wealth and competitive advantages for companies from their R&D and innovation activities. The development and implementation of sustainable strategies for IP exploitation require a concerted integration of the disciplines involved in order to achieve an interdisciplinary perspective on IP. In a knowledge-based economy, companies can only achieve a competitive edge by combining the economic, legal and technological sciences. IP management within such a holistic approach provides optimized appropriation strategies and thus essentially contributes to the creation of wealth within a company. Accordingly, IP management needs skilled managers who can combine the economics of intangible assets in an intellectualized environment with multidisciplinary knowledge in order to maximize the benefits of IP. A new type of competencies, skills and underlying knowledge enters the arena of management and management education. The increasing impact of intellectualized wealth creation by investment in knowledge, R&D and innovation followed by its exploitation and IP-based appropriation calls for seminal new education concepts. The CEIPI program "Master of IP Law and Management" offers such a new type of management education. It follows an intrinsically multidisciplinary approach to meet the challenges and requirements of the knowledge-based economy. This master program combines legal, economic and management sciences and includes lectures from leading scholars in the field of IP law and management. Its ultimate objective is to qualify experienced IP professionals for acting as practically skilled IP managers with a sound knowledge of the principles of wealth creation in our knowledge-based economy.

Alexander J. Wurzer
Director of Studies, CEIPI | Adjunct Professor
Director of the Steinbeis Transfer Institute Intellectual Property Management

Concepts of the Studies

Intellectual property and economics in the present context are two disciplines that exist in parallel.

Experts are found in each discipline, but with a lack of mutual understanding and training. Both "worlds" are nowadays bridged by experts, called IP managers, who link both disciplines through knowledge and experience. The CEIPI studies pursue a holistic approach and engage experts for the developing market of an IP economy. They are experts for basic economic management processes with specific assets. Management is understood in the broad sense of an overall company management and accordingly divided into six general functions:

- 1. Strategy
- 2. Decision
- 3. Implementation
- 4. Organization
- 5. Leadership
- 6. Business Development

On the basis of this differentiation skills should be allocated to management functions, and relevant knowledge to the functions and skills. The teaching concept focuses on both areas, skills and knowledge, as relevant to business with intellectual property.

Skills can be allocated to the specific management functions as relevant to the practical work within IP management. The skills are thus determined by the daily challenges and tasks an IP manager encounters.

For example, the "Decision" function includes skills such as "valuation and portfolio analysis techniques", and "Organization" as a function requires skills to manage IP exploitation and licensing including economic aspects as well as contractual design and international trade regulations with IP assets.

Special knowledge of economy and law is required in order to implement and deploy these skills in business. This includes knowledge of economic basics such as function of markets and internal and external influence factors. Additional management knowledge is also included such as value-added and value-chain concepts.

The legal knowledge includes contractual and competition law, and special attention will be paid to European and international IP and trade law, e. g. litigation, licensing, dispute resolution. Following this concept, IP law and management can be combined in clusters formed of specific skills and knowledge defined within each management function.

The lectures have a high international standard; the lecturers possess a high reputation and long experience in the teaching subject with academic and practical backgrounds.

The top-level experts come from the fields of law, economics and technology. The experts and the students work closely together during the seminar periods. Exchange of experience and, as a consequence, networking are common follow-ups.

Participants & their Benefits

This European master's program was designed especially for European patent attorneys, lawyers and other experienced IP professionals.

Its ultimate objective is to qualify experienced IP professionals to act as IP managers with the practical skills and knowledge to deal with the new challenges of wealth creation and profit generation. Participants acquire first and foremost a new understanding of how intellectual property works in business models and are conveyed the necessary skills to achieve the systematic alignment of IP management and business objectives.

The course provides an international networking platform for IP managers and in addition enables participants to build long-lasting relationships and to further develop relevant topics within the field of IP management. Being part of this international alumni network also offers new job opportunities and publication possibilities.

Past lecturers and academics

Prof. Jacques de Werra,
University of Geneva

Prof. Estelle Derclaye,
University of Nottingham

Prof. Christoph Geiger,
University of Strasbourg

Prof. Jonathan Griffiths,
School of Law, Queen Mary,
University of London

Dr. Henning Grosse Ruse-Kahn,
Faculty of Law, University of Cambridge

Prof. Christian Ohly,
University of Bayreuth

Prof. Christian Osterrith,
University of Constance

Prof. Yann, Ménière,
CERNA, École des mines de Paris

Prof. Cees Mulder
University of Maastricht

Prof. Julien Penin,
University of Strasbourg, BETA

Prof. Nicolas Petit
University of Liege

Prof. Alexander Peukert,
Goethe University,
Frankfurt/Main

Prof. Jens Schovsbo,
University of Copenhagen

Prof. Martin Senftleben
University of Amsterdam

Prof. Bruno van Pottelsberghe,
Solvay Business School

Prof. Guido Westkamp,
Queen Mary University London

Prof. Alexander Wurzer,
Steinbeis University Berlin

Prof. Estelle Derclaye,
University of Nottingham

Prof. Ulf Petrusson,
Göteborg University

Past lecturers and speakers, practitioners and institutions

Arian Duijvestijn,
SVP BG Lighting Philips

Kees Schüller,
Nestlé S.A.

Thierry Sueur
Air Liquide

Heinz Polsterer,
T-Mobile International

Dr. Fabirama Niang,
Total Group

Philipp Hammans,
Jenoptik AG

Dr. Lorenz Kaiser,
Fraunhofer-Gesellschaft

Leo Longauer,
UBS AG

Nikolaus Thum,
European Patent Office

Bojan Pretnar
World Intellectual Property Organization

Romain Girtanner
Watson, Farley & Williams

Peter Bittner,
Peter Bittner & Partner

Prof. Didier Intès,
Cabinet Beau de Loménie, Paris

Malte Köllner,
Köllner & Partner Patentanwälte

Dr. Dorit Weikert,
KPMG

Keith Bergelt,
Open Innovention Network

Selected companies

3M Europe S.A.
ABB Corporate Research Center
ABB Motors and Generators
AGC France SAS
Agfa Graphics
Air Liquide
Airbus Defence and Space
Akzo Nobel NV
BASF Construction Chemicals
Boehringer Ingelheim Pharma
British Telecom
Clyde Bergemann Power Group
Danisco/Dupont
DSM Nederland
Fresenius Medical Care
Groupe Danone
Jenoptik
Kenwood
Nestec Ltd
Novartis AG
Philips
Pilkington
PSA Peugeot Citroen
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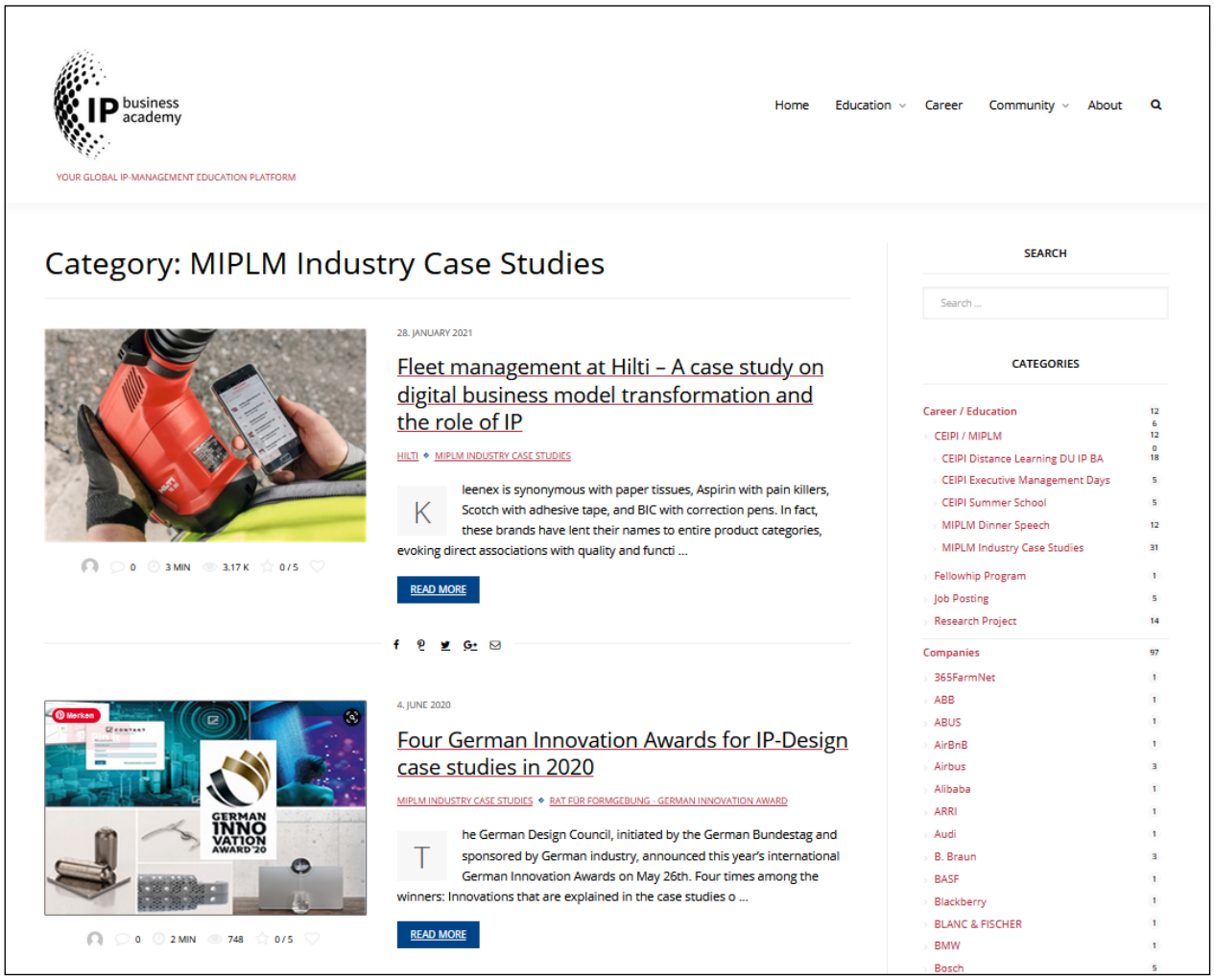

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