The Role of Law in Creating Space for Innovation: An Example from the Healthcare Sector in Germany

16

Roman Grinblat

16.1 Introduction

16.1.1 Current Relevance and Context

The urge for innovation is omnipresent and tangible. The relevance of the topic is clearly reflected in political programs at all levels. The EU Commission emphasizes the importance of innovation and promotes the "Innovation Union" as a flagship initiative for Europe (European Commission 2013). The TRIPS Agreement of the WTO mentions the "promotion of technological innovation" as a regulatory objective (Art. 7), and the OECD also repeatedly emphasises innovation as an objective (OECD 2020). The national government of Germany also targets the promotion of innovation (Bundesregierung 2018).

Innovation has long been the subject of various scientific disciplines. Independent disciplines of innovation research have been developed in economics, sociology, political science, psychology and the natural sciences (Engel and Morlok 1988; Towfigh and Petersen 2017). New disciplines such as neuroscience and creativity research are also adding new insights to the matter. However, the subject of "Innovation and Law" is not an independent or even in-depth subject of innovation research in Germany.

One of the few legal scholars in Germany dealing with innovation and law is the former Federal Constitutional Court judge Wolfgang Hoffman-Riem. He was the first in the German legal community to systematise legal innovation research (Hoffman-Riem 1997). His analyses cover a wide range of areas of law, including environmental law, telecommunications law, public procurement law and contract

R. Grinblat (✉)
Baden-Wuerttemberg Cooperative State University (DHBW), Heidenheim, Germany
e-mail: roman.grinbla@dhbw-heidenheim.de

V. Nestle et al. (eds.), *Creating Innovation Spaces*, Management for Professionals,
https://doi.org/10.1007/978-3-030-57642-4_16

law, in which the question of promoting innovation is discussed. However, a sector specific analysis of the type conducted in this chapter for the healthcare sector has not yet been conducted, leaving room for further research.

16.1.2 Definition of "Law" "Space" and "Innovation"

In order to discuss the role of law in creating space for innovation the terms "law", "space" and "innovation" must be defined.

16.1.2.1 Law

For the purposes of this chapter law includes not only national, international and European legal norms, but also sub-legislative regulations such as administrative regulations, case law and soft law.

16.1.2.2 Space

"Space" in this context is neither a physical or spatial concept nor a specific business area. Rather "space" is an environment allowing the creation, grow and spreading of innovations. It can include a multitude of different actors, such as consumers/patients, business stakeholders, political and other institutions such as research and educational institutions.

In literature the term "innovation ecosystem" is used (Glauner 2018; Grandstand and Holgerson 2020). This term is close to the understanding of "space" used in this chapter because an innovation ecosystem is characterised by a larger number of actors, where the actors are interconnected by exerting a mutual effect on each other. The members of an innovation ecosystem work cooperatively and competitively to support new products and services, to satisfy customer needs and to initiate the next round of innovation.

However, the understanding of "innovation spaces" used in this chapter differs from the "innovation ecosystem" in several respects. An innovation space is not necessarily product-driven or fixed on product innovation. It is not necessarily result driven and its evolution can affect social attitudes to a topic, which is not the primary goal of an innovation ecosystem. The normative incentive e.g. in the environmental law to introduce innovation can change a whole industry or even the point of view of a whole society. An innovation ecosystem in contrast does not contain millions of stakeholders or even the society as a whole.

16.1.2.3 Innovation

Depending on the discipline and its focus, the term innovation is defined differently (Hauschildt et al. 2016; Hoffman-Riem 1997; Mai 2014). This can perhaps serve as an explanation for the fact that, although innovation research has a long conceptual history (Godin 2015), to date there is neither a self-contained innovation theory nor a generally accepted definition of the concept of innovation (Hensel and Wirsam 2008). Based on the Latin word "innovatio", innovation means something new, renewal or novelty. Most contemporary definitions of 'innovation', seen as an

outcome of a process, rest on two defining characteristics, a degree of newness or change and a degree of usefulness or success in application of the newness. 'New' could mean new to the world, a particular nation, a group or even one firm.

The degree of usefulness or success in application of the newness are very important as these aspects distinguish innovation from invention. In the context of legal innovation research, the degree of usefulness or success in application equate with significance (Hornung 2015). Significance can be based for example on the following criteria (Hoffman-Riem 2016):

- Importance for the development of the legal system
- Legally effective solution of problems
- Scope in terms of content and time
- Recognition by courts
- Value in the scientific discourse and legal practice

Finally, Hoffman-Riem's legal innovation theory distinguishes between innovation through law and innovation in law (Hoffman-Riem 2016). A good example is environmental law, where innovative environmental protection measures have also been stimulated by legal requirements and where novel legal instruments such as environmental certificates and tradable rights for emissions are used. These two types of innovation—external and internal legal innovation—influence and complement each other (Hoffman-Riem 2010).

16.1.3 The Importance of Law in Innovation Research

Before discussing the role of law in creating space for innovation on the example of the healthcare sector, it is worth analysing the status quo.

According to Hoffman-Riem it can be observed in practically all studies from non-legal disciplines that law does not become the subject of closer analysis or part of theory formation even in disciplines intensively influenced by law (Hoffman-Riem 2016). The situation is made more difficult by the fact that, as already mentioned, innovation research is not yet able to carry out a decidedly differentiated and in-depth analysis of the use and possibilities of law. This may be due to the fact that in non-legal innovation research the law is seen more as an obstacle or a "Black-Box" rather than an accelerator.

Often other disciplines overlook the fact that law bears responsibility for innovation. This responsibility is embedded in the constitutional framework and is concretized by principles such as freedom of competition and science, equal opportunities, health protection and the guarantee of human dignity (Eifert and Hoffmann-Riem 2009). In essence, legal innovation research is also concerned with enhancing the common welfare—consisting of individual, group and societal interests.

Despite the common core scholars on legal innovation argue that in order to deal with the specific function of law in or as an object of innovation processes,

jurisprudential innovation research is largely dependent on itself (Hoffman-Riem 1997; Hoffman-Riem and Schneider 1998).

The situation in practice is different from that in academic discourse. In the healthcare sector large corporations, medium-sized companies as well as start-ups often need legal support for the introduction of innovation. It actually already starts in the development stage, during which, for example, IP law often plays a role, continues throughout the sales stage with drafting of contracts and ends with the diffusion of innovation (Rogers 2003). For the latter, amongst others data protection law, administrative law and liability law play an important role. Thus, there is a discrepancy between the stage of development of legal innovation research and the actual demand for legal advice and control of innovations. It would be advantageous if this gap were to be closed or at least narrowed.

This is particularly the case with innovations control, because not every innovation is automatically advantageous, as vividly illustrated by the example of the atomic bomb. In this respect, legal innovation management and responsibility as shown above has an extremely important role to play in the legal consultancy as well, e.g. regulation and advice on Genome-Editing such as CRISP/CAS 9 or TALEN technology (Transcription activator-like effector nuclease) (Deuring 2019; Bern 2020; Forum Bio-und Gentechnologie e.V. 2019).

16.2 German Healthcare System: A Normative Permanent Building Site for Innovation

The German healthcare system is a good example for illustrating the role of law in creating innovation spaces. Healthcare represents a highly socially relevant sector in which a wide range of companies and numerous groups of people are employed, much more than, for example, in the car industry (Statistisches Bundesamt 2020). Since 2017 healthcare expenditure in Germany has exceeded 1 billion euro per day (Statistisches Bundesamt 2020). It is an innovation-driven sector in which, for example, medical devices, in-vitro diagnostics, pharmaceuticals and bio-technology are subject to constant innovation pressure with partially average innovation cycles of 3 years (Medtech Europe 2018; BVmed 2007; VfA 2019; critical Glaeske and Ludwig 2018). The healthcare system is complex and has many sources of law, such as the German Social Security Code Book V (SGB V), the German Drug Law (AMG), German Medical Device Law (MPG) and European directives. This normative framework is subject to constant additions, deletions and revisions. Since its introduction in 1988 until the Medicines Restructuring Act (AMNOG of 22.12.2010), i.e. within 22 years, the SGB V has been amended more than 144 times. Thus, on average there has been a new amendment to the law every two months. The healthcare system can without hesitation be described as a permanent normative building site (Grinblat 2011). The amount of regulations allows an in-depth analysis of effects and consequences of the law on innovation spaces.

First, we need to note that when we talk about health care, we primarily mean the German statutory health insurance (SHI; Gesetzliche Krankenversicherung),

which covers about 90 percent of the insured population an where health services and medical products are reimbursed. Already because of the quantitative reasons innovation for patients plays an important role in this area. Private health insurance is of secondary importance in this context, although it naturally forms also part of the dual health care system in Germany.

The German SHI "market" is geared towards a benefit-oriented and at the same time economical provision of care, as expressed in the provisions of the SGB V. Thus, the benefits made available to the insured must be sufficient, appropriate and economical and may not exceed what is necessary; the quality and effectiveness of the benefits must correspond to the generally recognised state of medical knowledge and take medical progress into account (§§ 2, 12 SGB V).

Although the German social security market can certainly be described as robust, it did not exactly shine with its excessive implementation of innovations in the statutory benefits catalogue (Bundesrechnungshof 2019). The best example is the development of electronic health records (EHRs). The electronic patient file (ePA) will not be able to store important diagnosis and treatment data until January 1, 2021, in order to make health data available to practitioners across disciplines and sectors. Same issue applies for the electronic medical chip cards which are used nationwide by all the SHI-insured and were until recently not able to store even a drug medication plan.

There are different reasons for this fact. Firstly, it is related to the historical development, as the SHI in Germany and the corresponding law is based on the nineteenth century Bismarckian system and the Reichsversicherungsordnung (RVO). Thus, until recently, the word "digital" was not even mentioned once in the SGB V.

Secondly the German health care is based on a "neo-corporatistic" system with numerous special interests consisting of doctors, hospitals and sickness funds. Together with the National Association of Statutory Health Insurance Physicians, the National Association of Statutory Health Insurance Dentists and the German Hospital Federation, the National Association of Statutory Health Insurance Funds forms the Federal Joint Committee (Gemeinsamer Bundesausschuss/G-BA) which decides on the specific benefits to be included in the statutory health insurance catalogue.

Thirdly the introduction of innovations is made more difficult by the fact that in Germany we have completely different access routes for innovations in the outpatient and the inpatient sectors. In the German outpatient sector, new types of services and products (so called Neue Untersuchungs- und Behandlungsmethode/NUB) in the SHI system are generally prohibited and subject to permission, i.e. everything new is prohibited until it has been expressly permitted (§ 135 para. 1 sen. 1 SGB V). The G-BA is responsible for granting permission (§ 91 SGB V). It decides, in the form of guidelines, which new method may be used under which conditions at the expense of the SHI system in order to ensure sufficient, appropriate and economical care for the insured (§ 92 SGB V). Until recently, the evaluation procedure leading up to the decision of the G-BA could still take many years (Deutscher Bundestag 2018).

For services provided in the inpatient sector, permission is generally granted (BSG v. 06.05.2009—B 6 A 1/08 R). This means that new services and products may be provided in hospitals without prior examination as long as the G-BA has not explicitly excluded them (§ 137c SGB V). The legislator's guiding principle is to ensure that patients have rapid access to innovations (Deutscher Bundestag 2015). In this respect, parts of the literature argue that the normative framework in the inpatient sector favours the introduction and dissemination of innovations in the SHI system more than in the outpatient sector (Arnold et al. 2000; Vera and Salge 2008; Häckl 2010). However, this does not correspond to practice, as there are currently only a few ways to perpetuate innovations in the inpatient sector. The reason for this is the remuneration modalities for the provision of services in hospitals.

16.3 Law Promoting Digitalisation in Healthcare: The New DGV

So how can it be that under the above-mentioned circumstances law can promote innovation in the social health insurance? Some authors believe that innovations in the health care system can hardly be shaped by law (Knieps 1996). The Digital Care Act (Digitale-Versorgungs-Gesetz/DGV) which came in to force on December 18, 2019 shows the opposite (Federal Ministry of Healthcare 2019).

Already on the first page under the heading "Problems and Goals", the draft stated that under the current legal framework, the German health care system is only adaptive and agile to a limited extent in implementing digital solutions and new innovative forms of cooperation (Deutscher Bundestag 2019). Therefore, continued legislative adjustments are necessary in order to adapt the structures of the health care system to the dynamics of digital transformation and the speed of innovation processes. A remarkably open self-criticism of the German legislator.

16.3.1 Reimbursement of Digital Health Innovations and Fast-Track Procedure

To achieve this goal, the law aims, among other things, to bring digital health applications rapidly into supply. According to §27 para 1 S. 2 Nr. 3 Var. 5, §33a para 1 S. 1 SGB V the medical treatment includes the provision of digital health applications. In addition, a new evaluation procedure was created by further regulation (Digitale-Gesundheitsanwendungen-Verordnung/DiGA; Federal Ministry of Healthcare 2020). The procedure is designed as a fast track and takes three months. In this time frame the manufacturer must prove safety, functional capability, quality, data protection and data security and in particular a positive benefit effects of the health application. If it is not possible to prove positive effects on health care provision within three-month, digital health applications can initially be included in health care provision for a limited period of twelve months. During this time, the positive effects of the supply must be proven. However, this 12-month period could be extended up to another 12 months under the circumstances of § 139e IV 7 SGB V.

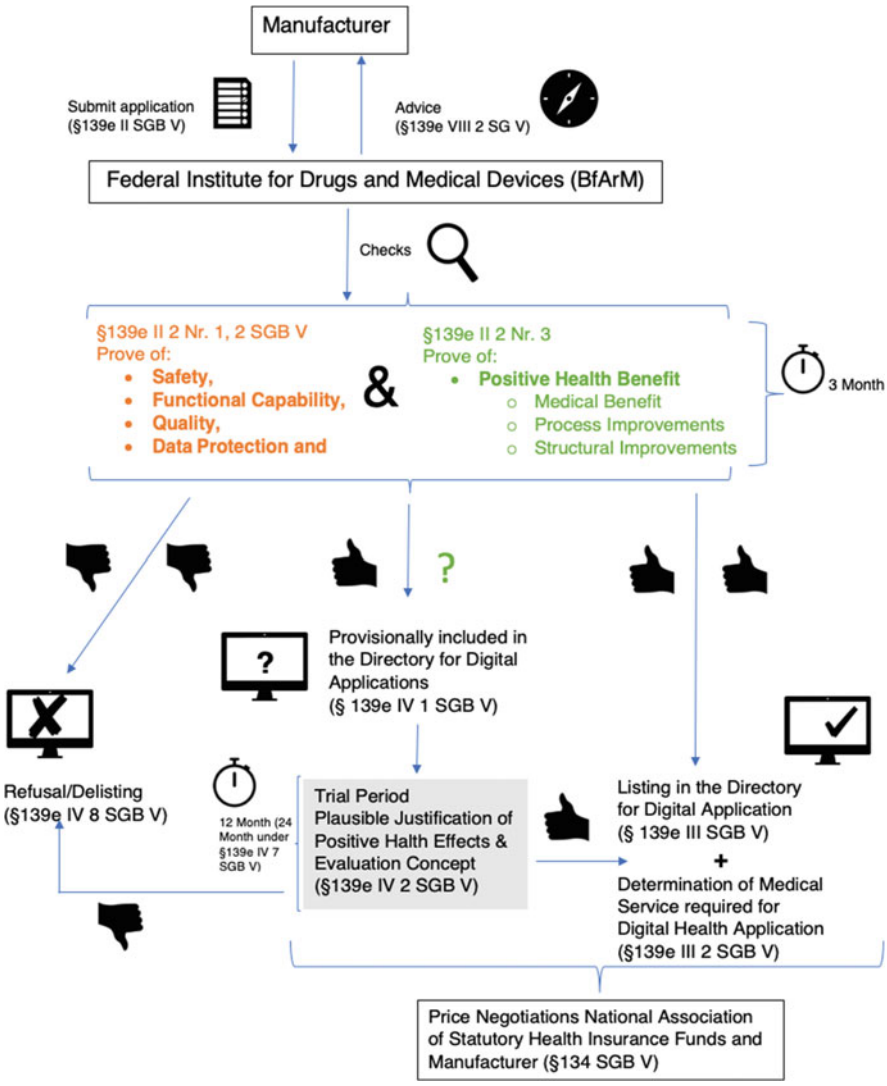

Fig. 16.1 Procedure of the fast-track for digital innovation. (Source: Author)

The responsible body for the approval procedure is the Federal Institute for Drugs and Medical Devices (BfArM). It also maintains an index of reimbursable digital health applications according to § 139e SGB V (BfArM 2020). For the overview and the relevant provisions of the fast-track procedure see Fig. 16.1.

The example of digital health apps illustrates at least three effects that law might have on innovation spaces.

- It has a direct steering effect on the innovative power of companies. With the prospect of cost reimbursement by health insurance companies and access to a potential 76 million insured people, start-ups in particular can receive venture capital and develop new products and/or develop existing products further.
- It accelerates network effects and cluster formation. Small, medium and large companies can join forces to penetrate the health care market. Especially as the financial risk is reduced by the bridging of 12 months.
- After all, the law contributes to a positive basic attitude or at least a rethinking of innovation among some stakeholders. Insured persons, doctors, health insurances and companies have to deal with the topic for various reasons. Irrespective of the outcome of this engagement process, the normative framework thus lowers the hurdles for a discourse on the topic.

In addition, the fast-track procedure shows very clear an internal legal innovation. This procedure has been newly anchored in the law and accelerates the introduction but also the dissemination of digital innovations. Because the regulation is very new and the index of reimbursable digital health applications is not available to the public yet, it remains to be seen, whether this innovation within the law will prove its worth or whether it requires further modification. The virtual DiGA summit with more than 1600 stakeholders from the health care sector and a planned English Summit can be seen as indications that innovative legal provisions can have an effect on innovation spaces and/or trigger innovation (Health Innovation Hub 2020).

16.3.2 SHI-Funds: The New Venture Capitalists?

Another innovative legal instrument is the possibility for health insurance funds to actively promote digital health innovations and also design the digital healthcare processes. They can develop digital health applications in cooperation with third parties or having them develop the application (§68a III SGB V). Furthermore, statutory health insurance funds can use up to 2 percent of their financial reserves to acquire shares in investment funds in the EU, EEA or Switzerland (§§68a IV Alt. 2, 263a SGB V). With 21 billion Euros of financial reserves (1.Q. 2019; Federal Ministry of Healthcare 2020a), this represents 420 million in venture capital.

These instruments represent an absolute novelty and have the potential to act as a catalyst for innovations in the German health care system.

16.4 Conclusion

As a result of this book chapter the following theses can be noted:

1. The topic of innovation through law and innovation in law is still underrepresented in legal research, especially in the field of healthcare.

2. The law is often regarded as an obstacle to innovation. However, the non-legal sciences fail to recognise that the law has a high degree of responsibility for innovation which is derived from the constitution.
3. In contrast to the more rudimentary legal innovation research, there is a high demand for legal advice on the introduction, implementation and dissemination of innovation.
4. Although some authors claim that law cannot directly influence innovation in healthcare, the DVG introduced in 2019 shows the opposite.
5. The introduction of digital health applications into the statutory health sector has a direct impact on innovation. It creates and strengthens the innovative power of companies, generates network and cluster effects and finally it can positively influence the attitude of many stakeholders in the health care sector towards digitisation.
6. The fast track procedure of the BfArM is a prime example of innovation in law, because it has anchored a new type of procedure in a legal system. The same applies to the legal possibility of venture capital of statutory health insurance funds.

References

Arnold M, Litsch M, Schnellschmidt H, Ackermann T (2000) Krankenhausreport 2000—Schwerpunkt Vergütungsreform mit DRGs 2001, 159 p

Bern CG (2020) Genome Editing in Zeiten Von CRISPR/Cas: Eine Rechtliche Analyse, 222 p

Bundesinstitut für Arzneimittel und Medizinprodukte (2020) Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 139e SGB V. Ein Leitfaden für Hersteller, Leistungserbringer und Anwender, pp 1–138. https://www.bfarm.de/DE/Medizinprodukte/DVG/_node.html. Accessed June 30, 2020

Bundesrechnungshof (2019) Bericht an den Haushaltsausschuss des Deutschen Bundestages nach § 88 Abs. 2 BHO über die Einführung der elektronischen Gesundheitskarte und der Telematikinfrastruktur, pp 1–41. https://www.bundesrechnungshof.de/de/presse-service/abonnements/berichte-rss. Accessed June 30, 2020

Bundesregierung (2018) Forschung und Innovationen. High Hightech-Strategie für Deutschland 2025. https://www.hightech-strategie.de/de/hightech-strategie-2025-1726.html

BVMed—The German Medical Technology Association, Cepton Consulting (2007) Nutzen durch Innovationen. Eine Studie zum Beitrag der medizintechnologischen Industrie zur Verbesserung der Gesundheitsversorgung in Deutschland. 1–60. https://www.bvmed.de/de/branche/innovationskraft/nutzen-durch-innovation. Accessed June 30, 2020

Deuring S (2019) Rechtliche Herausforderungen moderner Verfahren der Intervention in die menschliche Keimbahn. CRISPR/Cas9, hiPS-Zellen und Mitochondrientransfer im deutsch—französischen Rechtsvergleich, 505 p

Deutscher Bundestag (2015) Beschlussempfehlung und Bericht des Ausschusses für Gesundheit, BT-Drs. 18/5123 vom 10.6.2020. https://www.bundestag.de/drs. Accessed June 30, 2020

Deutscher Bundestag (2018) Report of the Chairman of the G-BA on compliance with deadlines in G-BA advisory procedures—German Parliament, Committee on Health, Committee printed matter 19(14)0009 vom 17.4.2018. https://www.bundestag.de/drs. Accessed June 30, 2020

Deutscher Bundestag (2019) Entwurf eines Gesetzes für eine bessere Versorgung durch Digitalisierung und Innovation (Digitale-Versorgung-Gesetz—DVG), BT-Drs. 19/13438 vom 23.9.2019. https://www.bundestag.de/drs. Accessed June 30, 2020

Eifert M, Hoffmann-Riem W (2009) Innovationsve rantwortung. Innovation und Recht III, 312 p

Engel C, Morlok M (1988) *Öffentliches Recht als ein Gegenstand ökonomischer Forschung*. Die Begegnung der deutschen Staatsrechtslehre mit der Konstitutionellen Politischen Ökonomie

European Commission (2013) Innovation union. A pocket guide on a Europe 2020 initiative, Luxembourg, https://doi.org/10.2777/59336

Federal Ministry of Healthcare (2019) Entwurf eines Gesetzes für eine bessere Versorgung durch Digitalisierung und Innovation (Digitale-Versorgung-Gesetz—DVG), BGBl. I Nr. 48, pp 2562–2584

Federal Ministry of Healthcare (2020) Verordnung über das Verfahren und die Anforderungen zur Prüfung der Erstattungsfähigkeit digitaler Gesundheitsanwendungen in der gesetzlichen Krankenversicheurng (Digitale-Gesundheitsanwendungen-Verordnung—DiGAV), BGBl. I Nr. 18, pp 768–798

Federal Ministry of Healthcare (2020a) Finanzreserven der Krankenkassen im 1. Quartal 2019 weiter bei rund 21 Milliarden Euro. DPA Meldung v. 20.6.2019. https://www.bundesgesundheitsministerium.de/presse/pressemitteilungen/2019/2-quartal/finanzergebnisse-gkv-1q-2019.html. Accessed June 30, 2020

Form Bio-und Gentechnologie e.V (2019.) Das große Dilemma: Genome Editing—verboten, aber nicht nachweisbar, https://www.transgen.de/aktuell/2742.genome-editing-nachweisverfahren.html. Accessed June 30, 2020

Glaeske G, Ludwig WD (2018) Innovationsreport 2018. Auswertungsergebnisse von Routinedaten der Techniker Krankenkasse aus den Jahren 2015 bis 2017. https://www.tk.de. Accessed June 30, 2020

Glauner P (2018) The artificial intelligence revolution, pp 67–78. In Innovationsumgebungen gestalten. Impulse für Start-ups und etablierte Unternehmen im globalen Wettbewerb, 277 p

Godin B (2015) Innovation contested: the idea of innovation over the centuries, 354 p

Grandstand O, Holgerson M (2020) Innovation ecosystems: a conceptual review and a new definition, Technovation, 90–91, 102098, pp 1–12. https://doi.org/10.1016/j.technovation.2019.102098

Grinblat, R. (2011) Rechtsfragen der Ausschreibung von Hilfsmitteln, 314 p

Häckl D (2010) Neue Technologien im Gesundheitswesen, p 162

Hauschildt J, Salomo S, Schultz C, Kock A (2016) Innovationsmangagement, 6. Edt. 479 p

Health Innovation Hub of the Federal Ministry of Health/hih (2020) DiGA Summit—Summary, Video, Docs, next steps. https://hih-2025.de/diga-summit-summary-video-docs-next-steps/. Accessed June 30, 2020

Hensel M, Wirsam J (2008) Diffusion von Innovationen. Das Beispiel Voice over IP, 120 p

Hoffman-Riem W (1997) Innovationen durch Recht und im Recht, pp 2–32. In Schulte M (Eds.) Technische Innovationen und Recht—Antrieb oder Hemmnis

Hoffman-Riem W (2010) Offene Rechtswissenschaft, pp 177–273

Hoffman-Riem W (2016) Innovationen im Recht, pp 11–31

Hoffman-Riem W, Schneider J-P (1998) Rechtswissenschaftliche Innovationsforschung. Grundlagen, Forschungsansätze, Gegenstandbereiche, 412 p

Hornung G (2015) Grundrechtsinnovationen, 674 p

Knieps F (1996) Arzneimittelinnovationen aus der Perspektive der Krankenkassen, pp 52–58. In Albring M, Wille E (Eds.), Innovationen in der Arzneimitteltherapie: Definition, medizinische Umsetzung und Finanzierung. https://doi.org/10.3726/b14079

Mai M (2014) Handbuch Innovationen. Interdisziplinäre Grundlagen und Anwendungsfelder. 369 p

Medtech Europe (2018) The European medical technology industry in figures, pp 1–44

OECD (2020) Science, technology and innovation outlook 2020, https://www.oecd.org/sti/science-technology-innovation-outlook/. Accessed June 30, 2020

Rogers EM (2003) Diffusion of innovations, 3rd ed, p 11

Statistisches Bundesamt (2020). https://www.destatis.de/DE/Themen/Gesellschaft-Umwelt/Gesundheit/_inhalt.html. Accessed June 30, 2020

Towfigh EV, Petersen N (2017) Ökonomische Methoden im Recht. Eine Einführung für Juristen, p 291

Vera A, Salge TO (2008) Innovationen im Krankenhaus—das Beispiel England. Das Krankenhaus 100(11):1184–1189

VfA/German Association of Research-Based Pharmaceutical Companies (2019) Positionspapier Pharma/Biotech und Innovationen, https://www.vfa.de/download/pos-pharma-biotech-innovationen.pdf. Accessed June 30, 2020