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The Interaction of Biotechnology and Institution: A Stakeholder Perspective

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Abstract: Institutional systems have a crucial impact on the development of biotechnology. In this article, we analyze the interaction between biotechnology and institutions. To conduct our analysis, we use the case study method and the stakeholder perspective. Our findings suggest the following: (1) Through the analysis of patent data, biotechnology has been developing very rapidly in recent years in China; (2) basic biotechnology institutions have been established, consisting of government, policy, and other institutional arrangements; (3) the interaction between the development of biotechnology and its existing institutions is dynamic; and (4) the interaction is affected by relative stakeholders. This study contributes to the theory concerning the governance of biotechnology, which is important in the sustainable development of biotechnology. Moreover, the article sheds light on policy implications.

Keywords: biotechnology; institution; interaction; stakeholder perspective; China

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1. Introduction

As an enabling technology [1], biotechnology can be applied broadly, which is very important for the economy, society, and environment [2]. Particularly, the discoveries, invention, and application of biotechnologies are leading to the emergence of the bioeconomy [3–5]. Nevertheless, recent biotechnologies have increasingly generated practical issues and regulatory challenges [6–8]. The misuse of biotechnology could be harmful to the environment or biodiversity, and concerns have been raised concerning the uncertainty of people's health, ethical issues, biosecurity, etc. [9]. At the end of 2018, the Chinese scientist Jian-Kui He claimed that he had helped create the world's first genome-edited babies using the CRISPR–Cas9 tool, and this raised global discussion [10–12]. At present, it is not clear what will happen to the two genome-edited babies, but what is known is that the scientist was sentenced to prison for 3 years [13]. Generally, the development of biotechnology and bioeconomy require the establishment and improvement of a regulatory framework [3].

In addition to practice, the development of biotechnology has received broad interest among researchers [6,9,14,15]. Prior studies have noted the importance of biotechnology-related institutions in various aspects [9,16–19], particularly in promoting the development of biotechnology [20]. However, together with the development of biotechnology, the related institutions also change dynamically. Although biotechnology potentially generates great benefits, the cost implications under certain circumstances might be massive, leading to public controversies and the need for intervention by institutions [9]. The relationship, particularly the interaction mechanism between biotechnology and institutions, is underexplored. Therefore, we ask the following research question: What is the interaction mechanism between biotechnology development and its institutions?

To answer our research question, we select China as a research context. China, as an emerging developing nation, with the aim of overtaking the curve, has achieved some improvements in the field of biotechnology [14]. In those years, China has paid considerable

attention to the development of the biotechnology industry [21]. In 2001, the biotechnology industry was listed as a high-tech industry in the 10th Five-Year Plan of High-tech Industry Development. In the Mid-Long Term S&T Development Plan (2006–2020), biotechnology is listed as the first of the eight types of cutting-edge technologies. The development of biotechnology in China has been very rapid in recent years. In accordance with the latest statistics by the OECD (key biotechnology indicators, available online: https://www.oecd.org/sti/emerging-tech/keybiotechnologyindicators.htm (accessed on 10 March 2022)), in 2018, China accounted for 8.2% of biotechnology patents from the IP5 patent families (the five largest IP offices in the world, including the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the National Intellectual Property Administration of the People's Republic of China (CNIPA), and the United States Patent and Trademark Office (USPTO)) only after the US (37.6%) and Japan (12.3%), while the percentage was only 0.8% in 2001. However, the institution that regulates and promotes the development of biotechnology is not established at first, and experiences a process to improve. This situation provides a proper foundation to examine our research question in China's context.

The reminder of the paper is organized as follows. In Section 2, we analyze the existing research on this topic. In Section 3, we introduce the research design. In Section 4, we present the situation of the biotechnology and relative institution. In Section 5, we analyze the role of stakeholders in the relationship between biotechnology and institutions. In Section 6, we present the main findings. Finally, Section 7 concludes our study.

2. Existing Research

2.1. Biotechnology and Institutions

Existing research on the relationship between technology and institutions increasingly focuses on the effects of institutions on technology [15,16,18,22]. The effects are mainly reflected in the following aspects. First, institutions stimulate and promote the research and development (R&D) of technology, and most countries in the world have put forward policies to support R&D activity [15,23]. Bronzini and Piselli [16] studied the impact of an R&D subsidy program on firm innovation, and found that the program had a significant impact on the number of patent applications. Second, institutions help protect technology and promote the commercialization of technology. The patent institution plays a crucial role [17]. In this case, Henderson et al. [18] found that the implementation of the Bayh-Dole Act has increased the extent of patent licensing.

In the field of biotechnology, OECD provides a framework for the function of policies, including supporting research, diffusing knowledge and expertise, commercializing biotechnology research, and encouraging the adoption (application and use) of biotechnology [19]. However, institutions also regulate R&D, and the commercialization of technology. This is mainly due to the fact that the use of biotechnology may pose risks to public health or the balance of the environment [9,22]. In the literature, Wiktorowicz and Deber [9] presented a political model for biotechnology regulation. Moreover, Stewart and Knight [22] studied the history of agricultural biotechnology regulatory policy in the US since 1972.

In addition, technology development pushes institutional change [24]. Evolution economist Nelson [25] analyzes the coevolution of technology and institutions in one of his early papers. With the development of technology, institutions may evolve at the same time, and this is particularly evident in the patent protection of biotechnology, since patentability for biotechnology in patent law has been revised in many countries. The development and application of biotechnology affects and is affected by a variety of stakeholders, and the institutions related to biotechnology are established in a system consisting of those stakeholders. We identify four types of key stakeholders in the relationship between biotechnology and institutions. The first is the government, which plays a central role in the institutional system and bioeconomy [26]. Governments intervene in the development and application of biotechnology by making policies, and taking institutional actions. The second is the industry, which acts as the link where technology is changed to be directly

helpful in the development of the economy. The bioeconomy consists of industries that rely on biotechnologies [3]. The biotechnology industry is stressed by governments not only due to the fact that it is necessary for the health of humans, but also due to the high profit from innovations. The third is the university and public research institute (U & PRI), which is a main producer of biotechnology. The fourth is consumers. Even though consumers do not have direct impact on biotechnology, they are greatly influenced by biotechnology, and they are cared for by the government when making policies.

Institution helps in reducing uncertainty. Therefore, organizations make rational choices by considering institutional factors, such as the state and society when making and implementing strategies [27,28], and this is how institutions influence the behavior of organizations [29]. At the same time, in the long run, institutions motivated by internal and external forces can also be affected and will change, as well [30]. In the field of biotechnology, different types of organizations are involved, and we combine the perspective of institutions and stakeholders to consider the more complicated interactions.

2.2. Stakeholder Perspective

In this study, we use a stakeholder perspective to analyze the relationship between biotechnology and institutions. Freeman's [31] seminal research on stakeholders promoted scholars' attention in this area. Since then, stakeholder theory has experienced an explosion of theoretical development over the past several years in one way or another [32], and has been broadly used in the literature [33–36]. Among these articles, the studies on policy [32,37], institution [38], and governance [39] are similar to the topic of the present research.

Carroll [40] defined stakeholder as "any individual or group who can affect or is affected by the actions, decisions, policies, practices, or goals of the organization". Donaldson and Preston [41] divided stakeholder theory into research of the "facts" (empirical description and summary) and "value" (normative core). Analysis based on the stakeholder perspective is required to consider the interests and concerns of different groups and individuals [32]. In solving the question in this research, both "facts" and "value" are stressed, since we care not only about the present relationship between biotechnology and institutions ("facts"), but also what the relationship should be ("value").

In our research, the interaction between biotechnology and institutions is a dynamic process, and is affected by various groups and individuals. At the same time, in a bioeconomy, the engagement of key stakeholders in the governance is an important theme to be stressed [7]. Therefore, the stakeholder perspective is particularly suitable here.

3. Research Design

3.1. Case Study

The case study method allows for the investigation of phenomena in their general complexity [42]. In addition, it is effective for research on a topic where the main aim is to find an answer to "what" and "how" questions [43]. The stakeholder theory provides a perspective and tool to understand the relationship between biotechnology and institutions, yet the relationship should be based on practice and evidence. Therefore, we select practical cases to explain the relationship.

In this analysis, three cases are selected. The first is the discussion of genetically modified food in China; the second is the "gene-edited babies" event in China; and the third is the development of vaccines and detection technology for COVID-19 in China. The three cases are used since (1) each of them is relevant to the development and application of biotechnology, and is closely related to institutions; (2) each of them is broadly considered in China.

3.2. Data Collection

3.2.1. Patent Data

We use patent application information to indicate the development of biotechnology. Patent is a frequent indicator used to measure technological innovation. Ahuja and Katila [44] use the number of granted patents to measure firms' innovation performance, and Carree et al. [45] use the number of patent applications per capita to measure regional innovation. In the field of biotechnology, patents are intensively used to protect inventions, and patent indicators can shed light on the level of biotechnology activity [2]. In accordance with a report by OECD [46], biotechnology patents represented 6.5% of countries' patent portfolios on average from 2004 to 2006.

The biotechnology-related patents are identified in Table 1, which is suggested by the OECD [47]. We obtain access to patent data through the database of Patyee (available online: patyee.com (accessed on 27 March 2022)), a broadly used commercial patent database in China, whose original patent data is extracted from the official patent database of the China National Intellectual Property Administration (CNIPO). We search data from 1985 to present (27 March 2022), and obtain 575,490 biotechnology patent application records in total. However, considering the time lag between patent application and publication, there is an underestimation of the exact number, since some recently submitted applications have not been disclosed.

Table 1. IPC codes of biotechnology patents.

IPC Section	IPC Codes
A (human necessities)	A01H1/00; A01H4/00; A01K67/00; A61K35/12-768; A61K38/00; A61K39/00; A61K48/00
C (chemistry; metallurgy)	C02F3/34; C07G11/00; C07G13/00; C07G15/00; C07K4/00; C07K14/00; C07K16/00; C07K17/00; C07K19/00; C12M; C12N; C12P; C12Q; C40B10/00; C40B40/02; C40B40/06; C40B40/08; C40B50/06
G (physics)	G01N27/327; G01N33/50; G01N33/53*; G01N33/54*; G01N33/55*; G01N33/57*; G01N33/68; G01N33/74; G01N33/76; G01N33/78; G01N33/88; G01N33/92; G06F19/10-24

Note: These IPC codes also include subgroups up to one digit (0 or 1 digit). For example, in addition to the code G01N 33/53, the codes G01N 33/531, G01N 33/532, etc. are included.

3.2.2. Case Information

The information for our case analysis is collected mainly from second-hand materials. These materials include: (1) Policy documents published by governments; (2) newspaper articles published by various newspapers in China; (3) books and journal publications; and (4) other online materials, e.g., announcements published by governments on their websites. Most of these materials are official publications or academic publications, and in the process of analysis, we use information from various sources to conduct mutual verification. Therefore, the information collected for case analysis is credible.

4. The Biotechnology and Relative Institutions

4.1. The Development of Biotechnology in China

Figure 1 shows the number of biotechnology patents in China during 1985–2020. Considering the time lag between patent application and publication, the numbers in 2021 and 2022 are not displayed. The number of biotechnology patents in 1985 was 198, and it reached 7359 in 2001, increasing by 36 times. In the 21st century, the number of biotechnology patents experienced an even sharper increase, rising to 49,850 in 2018.

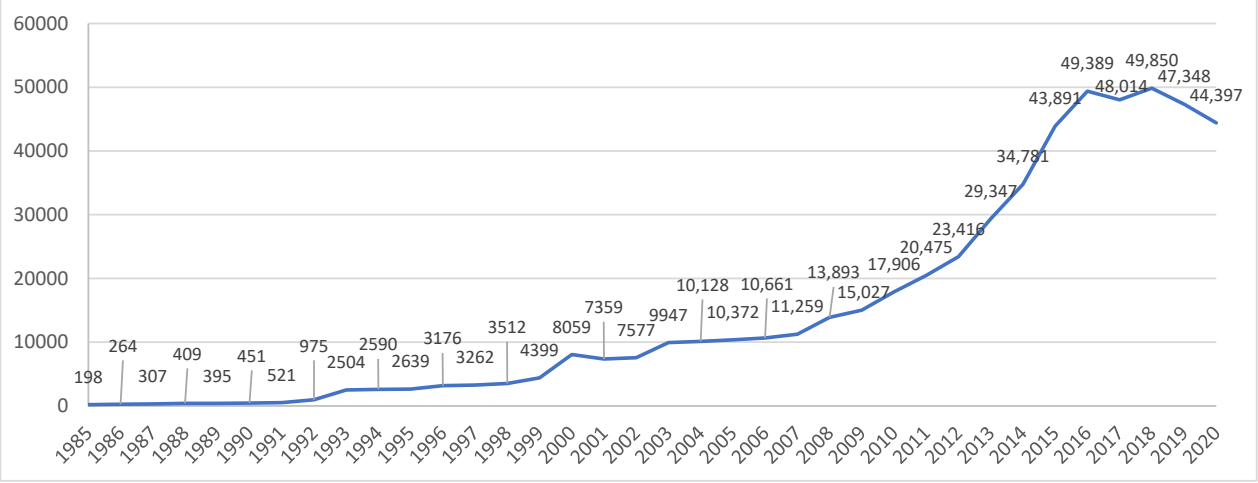

Figure 1. Number of biotechnology patents in China (1985–2016).

Figure 2 shows the 10 organizations with the most biotechnology patents in China. Jiangnan University ranks first with 5409 biotechnology patents. Among the top 10 applicants, there are only two companies: Biowindow Gene Development Inc. (Shanghai, China) in Shanghai ranks third with 3333 applications; the other is F. Hoffmann-La Roche Ltd., Basel, Switzerland, ranking ninth with 2189 applications. The remaining organizations are all domestic universities.

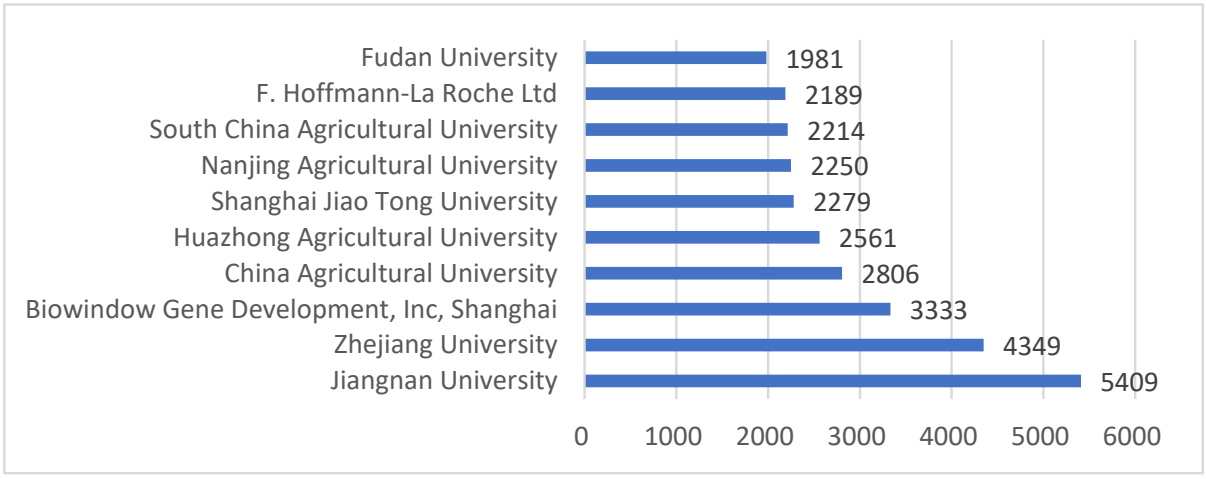

Figure 2. Main applicants of the biotechnology patents in China.

Figures 3 and 4 show the main IPC codes of biotechnology patents in China. Most of the biotechnology patents fall into the area of the class of A61K35 (medicinal preparations containing materials or reaction products thereof with undetermined constitution), C12N15 (mutation or genetic engineering; DNA or RNA concerning genetic engineering, vectors, e.g., plasmids or their isolation, preparation or purification; use of hosts thereof), and A61K36 (medicinal preparations of undetermined constitution containing material from algae, lichens, fungi or plants or derivatives thereof), with numbers of 135,610, 128,333, and 89,079, respectively. More specifically, C12Q1/68, C12N15/11, A61P35/00, C12N1/20, and A61K35/78 are the five subgroups that have the most applications.

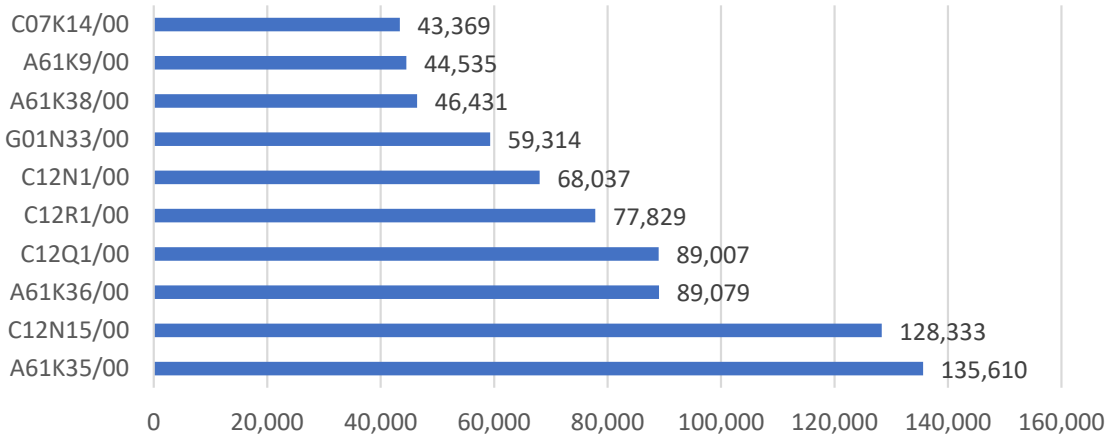

Figure 3. Main IPC codes of the biotechnology patents (main group).

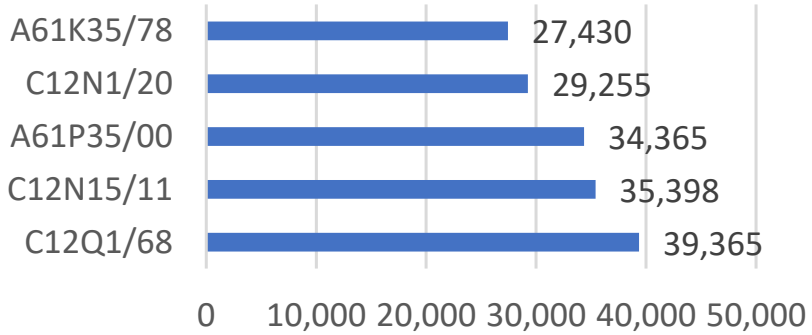

Figure 4. Main IPC codes of the biotechnology patents (subgroup).

Table 2 provides the number of biotechnology patents in different provinces in China. Jiangsu is the province with the most biotechnology patents, and the number is 55,238, followed by Beijing, Shandong, Guangdong, and Shanghai. Some western provinces, such as Ningxia and Qinghai, have a very small number of applications.

Table 2. Number of patents in different provinces.

Province	Number	Province	Number	Province	Number
Jiangsu	55,238	Guangxi	13,726	Jilin	7624
Beijing	51,007	Tianjin	12,851	Guizhou	5996
Shandong	49,088	Hunan	11,948	Jiangxi	5168
Guangdong	44,701	Liaoning	11,857	Gansu	4571
Shanghai	35,288	Fujian	11,193	Shanxi	4453
Zhejiang	29,073	Shaanxi	9327	Inner Mongolia	3245
Anhui	18,894	Heilongjiang	9311	Xinjiang	2762
Hubei	17,201	Chongqing	8122	Hainan	2546
Henan	17,168	Hebei	7915	Ningxia	1375
Sichuan	15,694	Yunnan	7780	Qinghai	777

Figure 5 shows the legal status of the biotechnology patents in China. Presently, 51% of the 575,490 total applications are invalid, accounting for more than half. As seen from the right part of Figure 5, 48% of the invalid patents are withdrawn, 26% of the invalid patents are rejected and thus not granted from the start, and 23% of the patents are invalid due to the non-payment of fees. A total of 2% of the biotechnology patents that expired were due to patent term completion.

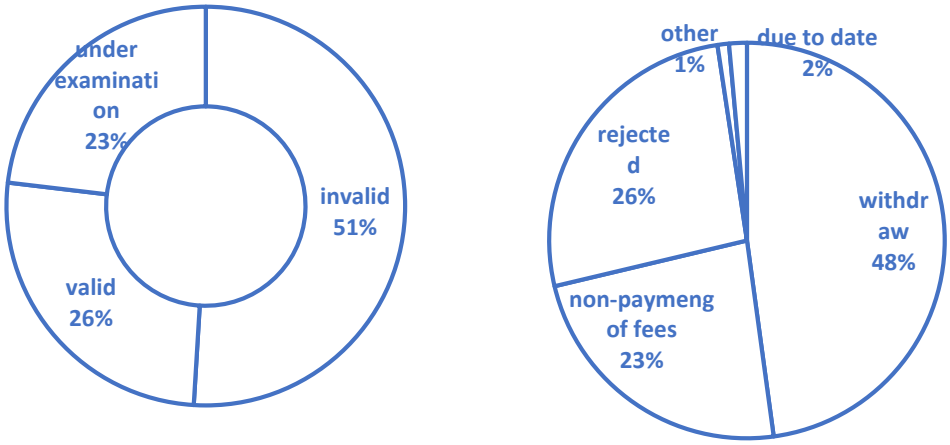

Figure 5. Legal status of biotechnology technology.

To explain the increase in the number of biotechnology patents, we investigate the funding of research projects by the National Natural Science Foundation of China (NSFC). The NSFC is the department responsible for the management of science funding in China. Presently, there are nine science sectors in different fields under NSFC, and one of them was established in November 2020. By 2021, NSFC granted research projects in eight science sectors: Mathematics and physics science, chemistry science, life science, earth science, engineering and material science, information science, management science, and medical science. Tables 3 and 4 show the funding situation in life science and medical science, which are closely related to biotechnology.

It is shown that the percentage of grants on life science projects has been sustained at a relatively high level, the value of which for general projects and youth projects is 19.21% and 17.45% in 2021, respectively. The total expense of medical science funding remains at a relatively high level; the amount for general and youth projects is 2497.68 and 1511.90 million Yuan in 2021, accounting for 22.53% and 24.07%, respectively. In 2021, the expense of general projects in the two fields accounted for 38.37% of the total expense of general projects, and the expense of youth projects in the two fields accounted for 37.62% of the total expense of youth projects. From this point, the government's investment might be a key factor in encouraging biotechnology patents from academic organizations.

Table 3. Funding on life science projects by the National Natural Science Foundation of China.

Year	General Project				Youth Project			
	# of Grant	% of Grant	Expense	% of Expense	# of Grant	% of Grant	Expense	% of Expense
2012	2706	20.44	203,880	16.34	2036	22.88	46,830	13.88
2013	2573	23.90	192,870	16.07	2233	24.71	51,380	13.89
2014	2313	26.59	189,910	15.91	2353	24.80	57,070	14.31
2015	2665	24.73	164,460	16.08	2214	23.38	44,310	13.87
2016	2700	24.99	162,990	16.02	2208	22.27	44,170	14.17
2017	2902	26.31	170,030	15.91	2395	22.67	57,460	14.36
2018	3048	24.07	177,470	15.91	2350	20.47	58,240	13.94
2019	3007	21.02	174,470	15.68	2428	17.96	58,240	13.84
2020	3029	15.78	175,672	10.45	2446	16.45	58,280	13.38
2021	3027	19.21	175,584	15.84	2855	17.45	85,110	13.55

Note: The general project is aimed at all types of applicants, the youth project is aimed at young applicants under a certain age, and the amount of funding for the general project is usually larger than the youth project. The unit for the expense is 10 thousand Yuan. Data source: Available online: https://www.nsfc.gov.cn (accessed on 10 March 2022).

Table 4. Funding on medical science by the National Natural Science Foundation of China.

Year	General Project				Youth Project			
	# of Grant	% of Grant	Expense	% of Expense	# of Grant	% of Grant	Expense	% of Expense
2012	4200	16.89	277,390	22.23	3007	18.79	69,430	20.57
2013	4072	20.98	268,670	22.39	3316	25.20	76,290	20.62
2014	3800	23.46	270,160	22.64	3502	19.50	80,560	20.19
2015	4102	20.94	230,940	22.55	3680	20.01	66,010	20.66
2016	4102	20.19	230,090	22.61	3720	18.01	64,710	20.76
2017	4455	19.40	242,140	22.66	4200	17.03	84,010	20.99
2018	4515	17.00	252,120	22.61	4222	15.19	88,680	21.23
2019	4584	15.99	252,120	22.66	4325	12.92	88,680	21.07
2020	4584	13.61	252,720	22.71	4505	11.74	107,520	24.68
2021	4534	13.79	249,768	22.53	5055	12.46	151,190	24.07

Note: Same as Table 3.

4.2. The Biotechnology Institution in China

The institution of biotechnology in China has also experienced evident dynamic development in recent decades. North [48] defined institutions as "the rules of the game in a society or, more formally, are the humanly devised constraints that shape human interaction". In addition, institutions are divided into formal institutions (e.g., laws, regulations) and informal institutions (e.g., cultural tradition, manners, and customs). In this paper, we only focus on formal institutions. Institution is broadly understood in this work, including government arrangement, policies, and other institutional arrangements.

4.2.1. Government Departments

There are several departments involved in biotechnology administration in China under the present governance structure. These departments include the Ministry of Science and Technology (MOST), Ministry of Industry and Information Technology (MIIT), State Administration for Market Regulation (SAMR), National Intellectual Property Administration (NIPA), National Development and Reform Commission (NDRC), etc., as shown in Table 5. These departments constitute the administration system of biotechnology in China, covering the aspects of research and development (R&D), industry development, supervision, and commercialization.

Table 5. Government departments involved in biotechnology administration.

Department	Main Responsibilities Related to Biotechnology
Ministry of Science and Technology (MOST), PRC	Establish science and technology (S&T) development plans and policies; organize and manage important S&T projects; provide human genetic resources regulation; promote the development and industrialization of biotechnology.
Ministry of Industry and Information Technology (MIIT), PRC	Establish plans, policies, and standards of high-tech industries concerning biotechnology.
State Administration for Market Regulation (SAMR), PRC	Food administration.
National Intellectual Property Administration (NIPA), PRC	Patent administration.
National Medical Products Administration (NMPA), PRC	Drug administration.
National Development and Reform Commission (NDRC), PRC	Establish plans and policies concerning innovation, entrepreneurship, and high-tech industry; promote the industrialization of new technologies.
National Energy Administration (NEA), PRC	Establish plans and policies concerning biomass energy.
Ministry of Agriculture and Rural Affairs (MARA), PRC	Agricultural living species; agricultural biology development.
National Health Commission (NHC), PRC	Food safety; examination of food safety-related new species; healthcare safety; supervision of biosafety in laboratories; technology standard.
State Administration of Traditional Chinese Medicine (SATCM), PRC	Chinese medicine administration.
Ministry of Commerce (MOC), PRC	Import and export of technologies.

Note: NIPA and NMPA are administered by SAMR, NEA is administered by NDRC, NFGB is administered by MNR, and SATCM is administered by NHC.

4.2.2. Policies

The policies related to biotechnology are an important part of the biotechnology institution. The present policy system can be analyzed from two dimensions. The first dimension is the administrative level of the department issuing the document, which can be divided into three types: (1) The law and other document issued by the National People's Congress (Table A1); (2) the regulations issued by the State Council (Table A2); and (3) the policy documents issued by the departments under the State Council (Table A3). The second dimension is the target area of the policies, and we divide the target into four types: (1) Technology development; (2) industry development; and (3) technology regulation (Table 6).

The main aim of "technology development" is to promote the R&D of biotechnology. As early as 1988, the General Office of the State Council (GOSC) issued the Critical Policy Points of Biotechnology Development to promote biotechnology. In the Mid-Long Term S&T Development Plan (2006–2020), biotechnology was listed as the first of the eight cutting-edge technologies. In 2011, the MOST issued two documents related to biotechnology development: The 12th Five-Year Plan of Biotechnology Development and the National Mid-Long Term Biotechnology Talent Development Plan (2010–2020).

The main aim of "industry development" is to promote the development of biology industries and biotechnology-related industries. In 2009, GOSC issued the Notice on Issuing the Several Policies in Promoting the Biology Industry Development. In 2001, the biotechnology industry was listed as a high-tech industry in the 10th Five-Year Plan of High-tech Industry Development. In 2010, the biology industry was listed as one of the seven strategic new-emerging industries in China. In 2012, the State Council issued the Bio-Industry Development Plan. In 2016, the NDRC issued the 13th Five-Year Plan on Biology Industry Development.

The main aim of "technology regulation" is to set limitations and standards for R&D and the application of biotechnology to avoid harmful or illegal effects resulting from biotechnology. Genetically modified food (GMF), biomedical ethics, and human genetic resources are the three most important issues. In 2019, the State Council issued the Regulation on the Management of Human Genetic Resources, and its last version was in 1986. In 2017, the State Council issued the amended Regulation on Administration of Safety of Agricultural Genetically Modified Organisms (GMO), which was first issued in 2001 and revised in 2011; the former Ministry of Health issued the Measures for the Ethical Review of Biomedical Research Involving Humans; and MOST issued the Management Measures on Safety of Biotechnology Research and Development.

As can be seen from the administrative level of the policies, most of them are in the second and third levels. On the first level, the Biosecurity Law, which was published in 2020, aiming at "promoting the healthy development of biotechnology", is the most relevant and the only law in the field of biotechnology. In the 14th Five-Year Plan, biotechnology-based industry is stressed, and a special section concerning biosecurity is included. On the second level, the State Council issues policies that are important in certain areas, and the State Council will transfer some important policies issued by the State Council departments in the name of the State Council to stress its importance by improving the policies' level from the third to the second level. The departments under the State Council issued policies in accordance with their responsibilities, and these are third-level policies, e.g., the MOST is in charge of technology development, and the NDRC is in charge of industry development.

Table 6. Main policies related to biotechnology.

Target Area	1st Level: Policies Issued by National People's Congress	2nd Level: Regulations Issued by the State Council	3rd level: Policies Issued by the State Council Departments
Technology development	- Outline of the 14th Five-Year Plan for National Economic and Social Development and the Vision for 2035 (National People's Congress, 2021)	- Critical Policy Points of Biotechnology Development (GOSC, 1988) - Mid-Long Term S&T Development Plan (2006–2020) (Stage Council, 2005)	- 12th Five-Year Plan of Biotechnology Development (MOST, 2011) - National Mid-Long Term Biotechnology Talent Development Plan (2010–2020) (MOST, 2011) - 13th Five-Year Plan of Biotechnological Innovation (MOST, 2017)
Industry development	- Outline of the 14th Five-Year Plan for National Economic and Social Development and the Vision for 2035 (National People's Congress, 2021)	- 11th Five-Year Plan on Biology Industry Development (GOSC, 2007) - Notice on Issuing the Several Policies in Promoting the Biology Industry Development (GOSC, 2009) - Bio-Industry Development Plan (State Council, 2012)	- 13th Five-Year Plan on Biology Industry Development (NDRC, 2016)
Technology regulation	- Biosecurity Law (National People's Congress, 2020) - Outline of the 14th Five-Year Plan for National Economic and Social Development and the Vision for 2035 (National People's Congress, 2021)	- Regulation on Administration of Safety of Agricultural Genetically Modified Organisms (State Council, 2001, revised in 2017) - Regulation on the Biosafety Management of Pathogenic Microbe Labs (State Council, 2004, revised in 2018) - Regulation on the Management of Human Genetic Resources (State Council, 2019) - Opinions on Strengthening the Governance of S&T Ethics (GOCC, GOSC, 2022)	- Measures for the Ethical Review of Biomedical Research Involving Humans (NHC, 2007, revised in 2016) - Management Measures on Safety of Biotechnology Research and Development (MOST, 2017)

4.2.3. Other Institutional Arrangements

Apart from the government departments and the policies concerning biotechnology, there are still some other institutional arrangements related to biotechnology in China.

The first lies in the R&D of the biotechnology: National Key Laboratory (NKL). China started to establish NKL in the 1980s, and at present, NKLs have become a very important part of the innovation system in China, particularly in the field of basic research. By the end of 2016, there were 254 NKLs in total, and 40 of them belonged to the area of biotechnology, accounting for 15.7% of the total number [49].

The second lies in the industry cluster of biotechnology. The development zones and biotechnology industry bases play an important role. In 2018, the NDRC issued the Content of the Chinese Development Zone (2018 edition), and the content includes all the national and provincial development zones certified by governments. Among all 552 national development zones, 88 have a dominant industry related to biotechnology, contributing to 15.94%. In addition, since 2005, the NDRC has granted 22 biotechnology industry bases with four batches [50], and these industry bases also play an important role in the development of technology and industry.

The third lies in the protection of biotechnology. China started to establish its patent system in 1985. Even though it has been regarded as weak in patent protection [51], the

government has made tremendous efforts to strengthen patent protection. The Patent Law, after its enactment, was revised four times in 1992, 2000, 2008, and 2020. In 2014, the Chinese government decided to establish three specialized intellectual property (IP) courts in Beijing, Shanghai, and Guangzhou to deal with increasing IP litigations.

5. Stakeholders in the Relationship between Biotechnology and Institution

In this section, we apply the stakeholder perspective to analyze the relationship between biotechnology and institutions.

5.1. Case Description

5.1.1. Discussion on the Safety of Genetically Modified Food (GMF)

Discussion on the safety of GMFs is a real-world issue [52], and has lasted for quite a long time in China [53]. On 27 October 2009, the MOA in China issued three safety certificates for transgenic crops, indicating that these crops were planned to be commercialized. However, safety issues have been broadly discussed, and Table 7 shows some key milestones in the process.

Table 7. Timeline of the discussion on genetically modified food.

Time	Progress
23 May 2001	The State Council issued the Regulations on Administration of Agricultural Genetically Modified Organisms Safety.
5 January 2002	The MOA issued the Evaluation Method on the Safety of Agricultural Genetically Modified Organisms.
2 June 2003	The first lawsuit concerning the GMO labelling in China was accepted by a court in Shanghai.
9 December 2004	The journal "Southern Weekly" published a paper "transgenic corn: A game of safety and benefit for 1.3 billion people?" and discussed the use of transgenic food.
27 October 2009	The MOA issued safety certificates for two strains of transgenic rice and one strain of transgenic maize.
1 August 2012	Tang et al. published the article "β-Carotene in Golden Rice is as good as β-carotene in oil at providing vitamin A to children", mentioning that some children in China were selected to provide transgenic rice to conduct the experiment.
6 December 2012	The Chinese Center for Disease Control and Prevention issued a notification on the investigation of Tang et al.'s paper, declaring that the activity violates the "Measures for the Ethical Re-view of Biomedical Research Involving Humans" and research ethic principles.
7 September 2013	A science writer named Zhou-Zi Fang, promoted an activity to eat transgenic maize.
25 October 2013	CCTV broadcasted that the MOA is conducting an experiment to feed animals with transgenic maize.
25 October 2013	A prefectural city named Zhangye, under Gansu Province, issued a policy named "Opinion on Establishing a safe city of agricultural products", that has forbidden GMO in the city.
20 December 2013	A former presenter named Yong-Yuan Cui, shared his experience of entering the US to investigate transgenic food on his own charge.
2 March 2014	Yong-Yuan Cui, who is also a member of the national committee of Chinese People's Political Consultative Conference (CPPCC), in the media interview during the 12th Session, indicated that some provinces in China are illegally planting transgenic maize.
September 2014	An attorney named Si-Long Xu started an activity against the unclear labelling of GMO. A total of 87 people participated in the activity, and 71 of them were attorneys. By 7 October 2014, they have filed 11 lawsuits, and nine of them had been accepted by courts.
1 February 2015	The Central Committee of the Communist Party of China (CPC) and the State Council issued the policy "Several opinions on improving reform and innovation, accelerating agricultural modernization", which is also known as the annual No. 1 Document issued by the central government in China. The required document strengthened the technology research, safety management, and science popularization of agricultural genetically modified organisms.
2 August 2017	The Chinese Society of Agricultural Biotechnology issued the "Truth of the ten Rumors about Transgenesis".

5.1.2. The "Gene-Edited Babies" Event

On 26 November 2018, a Chinese scientist, Jian-Kui He, declared that two of the world's first genetically edited babies who are immune to HIV infection were born. This event raised broad worldwide attention and criticism concerning Jian-Kui He's activity. Table 8 shows some key milestones in the event.

Table 8. Timeline of the "gene-edited babies" event in China.

Time	Progress
26 November 2018	Jian-Kui He, associate professor at Southern University of Science and Technology, China, declared that two of the world's first genetically edited babies who are immune to HIV infection are born in China.
26 November 2018	The Southern University of Science and Technology, where Jian-Kui He works, published a statement declaring that the research was conducted by Jian-Kui He outside of the university without their knowledge, and that the research seriously violates academic ethics.
26 November 2018	The Expert Committee on Medical Ethics in Shenzhen started the investigation.
26 November 2018	A joint statement signed by 122 scientists was issued, expressing disapproval and condemnation.
26 November 2018	The NHC issued a statement requiring the Guangdong health commission to investigate the event.
26 November 2018	The NHC, together with MOST, issued a statement stressing that the science research and medical activities should comply with laws and ethics.
27–28 November 2018	The Chinese Academy of Sciences, the Chinese Academy of Engineering, and the Chinese Academy of Medical Sciences, the China Association for Science and Technology, all published statements expressing disapproval.
21 January 2019	A newspaper by the Xinhua News Agency disclosed that the event of gene editing activities in human embryos, which is prohibited by law, was conducted by Jian-Kui He in pursuit of personal fame.
21 January 2019	The NHC issued a statement declaring that the event seriously violates the law and ethical principles in China.
1 January 2019	The Southern University of Science and Technology, where Jian-Kui He works, published a statement declaring that the labor contract relationship with Jian-Kui He was terminated.
30 December 2019	The Nanshan Court announced that Jian-Kui He was guilty of illegal medical practice; the three defendants (including Jian-Kui He) were sentenced to 3 years in prison along with a fine of 3 million Yuan.
26 December 2020	The amendment (XI) to the Criminal Law added contents concerning gene edition.

5.1.3. The Development of Vaccine Sand Detection Technology for COVID-19

At the end of 2019, the explosion of COVID-19 has spread throughout the world with strong impacts in various dimensions. The pandemic has brought significant losses to human life and the economy. To cope with the virus, the Chinese government adopted several measures to develop vaccines. The development, clinical trial, and approval of a vaccine typically last several years. However, China has shortened this process to several months with the development of different solutions through various approved COVID-19 vaccines. Institutions play important roles in the process, and some of the key milestones are shown in Table 9.

Table 9. Timeline of COVID-19 vaccine development in China.

Time	Progress
End of 2019	The first case of COVID-19 was confirmed in Wuhan, Hubei Province, China.
2–12 January 2020	The Wuhan Institute of Virology (WHIOV) identified the complete genome sequence of COVID-19 on 2 January, obtained the isolated strain on 5 January, and provided the genome sequence information to the World Health Organization (WHO) on 12 January. Later, the WHIOV provided the strain to several research organizations.
January 2020	The Chinese government planned five roadmaps of technology to develop the vaccine. The Chinese Academy of Sciences initiated the specialized research project "COVID-19 Prevention and control at emergency". The National Natural Science Foundation of China (NSFC) announced a specialized call for research on COVID-19.
January 2020	(i) On 19 January, the company China National Biotec Group (CNBG), a branch under China National Pharmaceutical Group Co., Ltd., Beijing, China (Sinopharm), established a leadership group and started the R&D of the COVID-19 vaccine, led by the scientist and president Yang Xiao-Ming. CNBG planned two lines to conduct the research, cooperating with WHIOV, National Institute for Viral Disease Control and Prevention (China CDC), etc. (ii) On 28 January, the company Sinovac Biotech Ltd. (Beijing, China) initiated a project named "Anti COVID-19 Action" to develop an inactivated COVID-19 vaccine. Sinovac cooperated with the Institute of Laboratory Animal Sciences (CAMS & PUMC), the Chinese Center for Disease Control and Prevention, etc., to conduct the research.
1 February 2020	The MOST approved a specialized program "Inactivated vaccine of 2019-nCoV" (No. 2020YFC0842100) under the National Key Research and Development (R&D) Program Project "Risk Prevention of Public Safety and Emergency technical equipment".
8 February 2020	The MOST published a call for program application aiming at fast on-site detection products of COVID-2019.
March to April 2020	(i) On 16 March, the vaccine developed by the group led by Chen Wei (researcher at Military Medical Research Institute) entered into a period of clinical trial for the first time worldwide. (ii) On 12 April, the vaccine developed by Wuhan Institute of Biological Products Co., Ltd., Wuhan, China (a branch under Sinopharm) was approved to conduct clinical trial. (iii) On 13 April, the vaccine developed by Sinovac was approved to conduct clinical trial. (iv) On 27 April, the vaccine developed by Beijing Institute of Biological Products Co., Ltd., Beijing, China (a branch under Sinopharm) was approved to conduct clinical trial.
June 2020	The vaccine developed by Sinovac was approved for emergency use in China.
30 December 2020	The vaccine developed by Beijing Institute of Biological Products Co., Ltd., a branch under Sinopharm, was approved for sale in the market by the NMPA when relevant conditions are met.
31 December 2020	The first COVID-19 vaccine entered the market in China.
5 February 2021	The vaccine developed by Sinovac was approved for sale in market by the NMPA when relevant conditions are met.
25 February 2021	(i) The vaccine developed by Wuhan Institute of Biological Products Co., Ltd., a branch under Sinopharm, was approved for sale in market by the NMPA when relevant conditions are met. (ii) The vaccine developed by CanSino Biologics Inc. (Tianjin, China) was approved for sale in market by the NMPA when relevant conditions are met. This vaccine is in cooperation with the research group of Chen Wei.
February 2021	The National Healthcare Security Administration (NHSA) required that the cost of a single person's independent test for nucleic acid detection of the novel coronavirus should be no more than 80 Yuan.
10 March 2021	The vaccine developed by the Institute of Microbiology, Chinese Academy of Sciences, and the cooperated company was approved for emergency use in China.
September 2021	Most provincial governments in China required that the cost of a single person's independent test for nucleic acid detection on the novel coronavirus should be no more than 60 Yuan.
15 December 2021	The NHSA required that the cost of a single person's independent test for nucleic acid detection on the novel coronavirus should be no more than 40 Yuan after 15 December 2021.
25 March 2022	The NHSA published the policy document on Strengthening the Price Management of Antigen Detection on New Coronavirus.
1 April 2022	The NHSA required that the cost of a single person's independent test for nucleic acid detection on the novel coronavirus should be no more than 28 Yuan.

5.2. The Function of the Main Stakeholders

5.2.1. Government

Various government departments function simultaneously in administrating biotechnology from different angles, including the development of technology and industry, protection of invention, as well as supervision of food and medicine. The direct users of institutions include universities, industries, and consumers. The main functions of governments include: (1) Providing funding for the research of biotechnology in U & PRI, and regulating the research activity; (2) providing funding for the research and development of biotechnology in industry, regulating their research activity and production, and providing preferential policies (e.g., preferential taxation policy); and (3) creating policies to protect and benefit consumers, e.g., their right to know the information of GMF.

In the case of GMF safety, the main function of the government is to establish policies concerning genetically modified crops and GMF, set standards on the marketing and selling of GMF, and issue certificates to products of GMF. In the case of the "gene-edited babies" event, the government plays an important role, even though the government failed to avoid this event, yet several measures had been taken after the event, e.g., the punishment of the responsible scientist, the improvement of relative policies, especially the amendment of the Criminal Law and the issuance of the Biosecurity Law. In the case of COVID-19-related technologies, the government plays a significant role in promoting the fast development, approval, and production of the vaccines. Moreover, the government created policies to control the cost of detection of the novel coronavirus. This measure is based on the development of new efficient detection technologies and products, and is helpful for consumers.

5.2.2. Industry

The role of industry concerning biotechnology is reflected not only in producing products and selling them to consumers, but also in the R&D activity of biotechnology. Moreover, the industry has an important power on biotechnology research. The activities of industry are greatly affected by institutions. From the perspective of innovation value chain, first, the industry can apply for government funding projects to conduct R&D, and enjoy the reduction in taxes by conducting R&D. Second, institutions provide patent protection for the industry, guaranteeing their monopoly income. Third, by selling biotechnology products, the industry can again enjoy the reduction in taxes under certain conditions. At the same time, the development of industry influences the evolution of institutions. When the industries are weak in biotechnology and market power, they require the government to provide more public funding in R&D and provide protection to relatively weak patents for the industry to grow. With the development of the industry, they can in turn, be stronger in technology and apply for additional patents, which requires stricter patent protection from the government.

In the case of GMF safety, the development of the relative biotechnology industry required the legitimation of the GMF. Therefore, they are motivated to invest more in biotechnology R&D, and to push the government to formulate policies to identify their role. In the case of COVID-19-related technologies, the industry made important contributions to developing vaccines, such as the Wuhan Institute of Biological Products Co., Ltd., Sinovac Biotech Ltd., and CanSino Biologics Inc.

5.2.3. University and Public Research Institute (U & PRI)

U & PRIs are the most important contributors to biotechnology development in China. They sell or license out the technology to industries, and then the technologies are commercialized to industries, that in turn, are introduced to the market. Fiscal expenditure is an important source of research funding. Meanwhile, universities may also receive funding from industry or establish laboratories in alliance with industry. At the same time, the R&D activities in U & PRI are regulated by the institution, and the U & PRI also establish internal rules to regulate the behavior of their employed scientists.

In the case of GMF safety, transgenic rice that received the first two safety certifications was developed by the research team at Huazhong Agricultural University. In the case of "gene-edited babies", scientist Jian-Kui He is a professor of the Southern University of Science and Technology. Even though the university tried to stay out of trouble, there is no doubt that the university is responsible for administering its staff. In the case of COVID-19-related technologies, various research groups from the U & PRIs are involved in research on vaccines to promote the innovation process.

5.2.4. Scientist

Scientists are the direct entities that conduct the R&D of biotechnology. Similar to the role of U& PRI, scientists receive funding from the institution to conduct research, and the institution encourages their innovation work. At the same time, their research work is regulated by the institution, and should comply with the policies.

In the case of GMF safety, scientists play a significant role in promoting the commercialization of GMFs. For example, a scientist named Qi-Fa Zhang, who is an academician of the Chinese Academy of Sciences, delivered speeches and comments concerning the safety and advantages of GMF several times. In fact, he is also the principal scientist in the research project of transgenic rice, which received the first two safety certifications in China. Another example lies in the activity of the Chinese Society of Agricultural Biotechnology in issuing the "Truth of the ten Rumors about Transgenesis", which is helpful for consumers to better understand and accept GMF. In the case of "gene-edited babies", many scientists criticized Jian-Kui He's scientific misconduct and violation of research ethics. In the case of COVID-19-related technologies, individual scientists are also important in leading the research, such as Chen Wei from the Military Medical Research Institute, and Yang Xiao-Ming from CNBG.

5.2.5. Consumer

The food that people eat and the medicine that people use are all related to biotechnology. In the process of dealing with those items, consumers will provide feedback to the industry and government, thus influencing their decisions. In the case of GMF safety, consumers think they have the right to clearly know whether the products they buy are genetically modified crops. When consumers find that their rights are not respected, they safeguard themselves by filing lawsuits, which attracts the attention of the government to improve institutions. In the case of COVID-19-related technologies, consumers have a high and frequent need for nucleic acid detection of the novel coronavirus, and this requirement forms a huge market and encourages the development of new technologies. At the same time, the opinion of the consumers also influences the government's decision in controlling the price.

6. Main Findings

6.1. Biotechnology Interacts with Institution Dynamically

The basic framework of biotechnology institutions has been established in China. There are different departments in charge of different administrative areas of biotechnology. Various laws, plans, regulations, and other policies concerning biotechnology have been issued. Different institutional measures are taken to promote the development of the biotechnology and biotechnology industry, e.g., the NKL and the development zone.

Institution co-evolves together with the development and application of biotechnology. However, the growth of biotechnology research is very rapid, while the improvement of institutions is relatively slow. Therefore, institutions require time to step up the pace. Thirty years ago, China has noticed the importance of biotechnology and biotechnology industry, since the GOSC put forward a policy to promote biotechnology in 1988. Even though the government issued a policy concerning the safety of agricultural GMOs as early as 2001, this did not prevent the intense discussion concerning the safety of GMFs in society when the GMFs were placed in the market, and consumers' worries were not relaxed by the

policy. The GMF institutional system gradually improved in recent years, and the 2001 GMO-safety-related document was amended until 2017.

The improvement of institutions is pushed by the development and application of biotechnology. In the case of "gene-edited babies", although the responsible scientist was punished, the name of the crime was "illegal medical practice". However, to some degree, it is not fully suitable to judge who is guilty in this event. The crime of "illegal medical practice" should be based on the fact of "medical practice", while the activity of Jian-Kui He was more of "medical research" rather than "medical practice", and the role of Jian-Kui He was a researcher rather than a doctor. The event of "gene-edited babies" directly led to the amendment of the Criminal Law in China in 2020, and a new article was added, defining a new crime named "crime of illegally implanting gene editing and cloning embryos", which is targeted at a similar activity with the "gene-edited babies".

6.2. The Interaction between Biotechnology and Institutions Is Affected by Stakeholders

A variety of stakeholders function in the interaction between biotechnology and institutions, and the interaction mechanism is affected by a system consisting of all stakeholders (Figure 6).

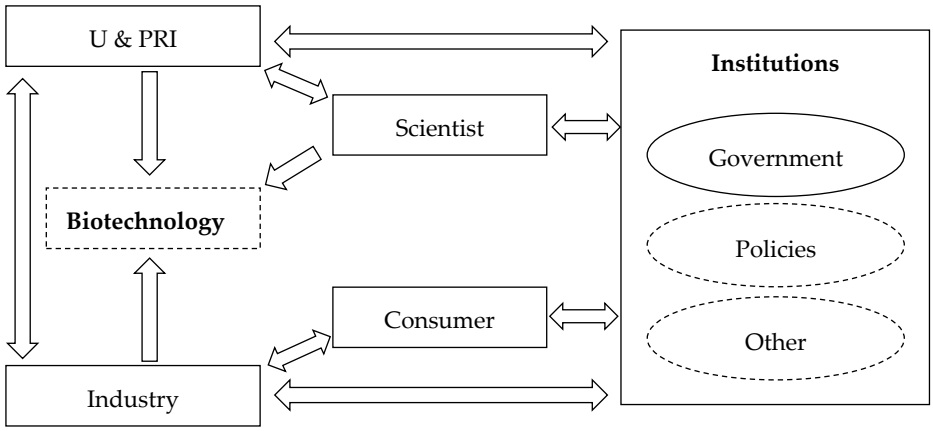

Figure 6. Interaction mechanism of biotechnology and institutions. The main stakeholders are depicted in the solid line box; and in the dotted line box, main elements that cannot be defined as stakeholders are shown.

Biotechnology is developed through various mechanisms: (1) U & PRIs and their scientists conduct research on biotechnology to obtain academic reputation; (2) industries also invest in R&D on biotechnology to achieve market return, and they sometimes cooperate with U & PRIs; and (3) the government encourages the development of biotechnology in U & PRI and industry to drive the progress of the economy and society. However, the R&D of biotechnology may be misconducted, and biotechnologies may be improperly used. Therefore, policies to regulate the technologies are required. In the absence of specific regulation, the occurrence of an emergency incident can speed up the process of institutional progress. However, society will undertake the cost brought by the emergency.

7. Concluding Remarks

7.1. Conclusions

This article presents an update on biotechnology-related institutions in China. We study the interaction mechanism of biotechnology and biotechnology-related institutions under the context of China. As can be seen from the number of patent applications, the development of biotechnology has improved considerably. Universities that are supported by public funds are an important contributor, in line with prior findings [3,14]. The institution concerning biotechnology consists of governments, policies, and other institutional

arrangements. It is found that biotechnology co-evolves with the institution, and the interaction is affected by various stakeholders.

The roles of institutions in biotechnology are mainly reflected in two aspects: Promotion and regulation. First, the R&D and experiment of biotechnology usually takes a long time and faces great risk, and this requires the government to take action. This may be part of the reason why universities patent a lot of biotechnology, considering that they can receive more research funding from government than companies. Second, the R&D and application of biotechnology may have a negative impact on food safety, medicine safety, and biodiversity. Biotechnology is usually concerned with ethical issues, and new biotechnologies of cloning technology, artificial insemination, and test-tube baby challenge traditional perceptions. Moreover, these technologies have a potential influence on the evolution and development of human beings, of which we still do not know whether the influence is good or not. Biotechnologies used in optimizing crops may be harmful to ecological balance and biodiversity, and eating GMF still has uncertainty for people's health. Biotechnology has the possibility of use as virus in war. All of these require governments to set standards to regulate the behavior of stakeholders.

7.2. Discussions

The development of biotechnology is important in the context of the bioeconomy [5,54,55], and the establishment of an efficient regulatory system is required [3] as a major influencing factor of the bioeconomy [7]. Technological innovations are a powerful driver in promoting economic development, but may result in severe social or environmental issues if not well regulated [56,57]. To reach a sustainable development goal, the benefits and potential adverse impacts require balance, with the role of different stakeholders considered. Motivated by these drivers and opportunities, this article analyzed the institutions of biotechnology.

This research mainly contributes to research on technology governance [56,58–61], particularly biotechnology governance [57,62–64]. "With the increasingly prominent position and the important role of biotechnology in national development systems", it is necessary to achieve good governance by establishing fair laws and regulations [62]. However, "creating new institutions is always a challenging task and should not be undertaken lightly" [59]. Prior studies on this topic have increasingly focused on the context of developed countries [65–70]. However, this issue is also important in developing countries, where biotechnology has developed quickly and, if not properly regulated by institutions, may cause severe problems, such as the event of "gene-edited babies" in China. In recent years, China has taken various measures to catch up with developed countries in the field of science and technology. However, institutions cannot keep up with new technologies, particularly in developing countries where increased attention has been provided to the economic-growth effect of technology rather than the potential harm. With the use of China as a context, we explain how biotechnology interacts with institutions.

7.3. Implications

Based on the above analysis, we achieved the following implications, mainly for policy makers. First, even though a large number of biotechnology patents are submitted in China, this may not indicate that the real technological innovation level has improved equally. Universities are an important contributor to biotechnology patents, yet most of those patents are generated by undertaking government-funded research projects. In addition, professors are motivated to apply for patents since they can receive faster promotion. As a result, many patent applications are of low quality and are difficult to use in the industry. Therefore, investment in the R&D of biotechnology still requires increased attention and leans toward the private sector. The role of universities and industries in the innovation system of biotechnology should be clarified. Industry should be at the core of the system, and firm innovators are strongly required. Even though the government in China has taken measures to cultivate the biotechnology industry, the effect is required for evaluation and strengthening.

Second, although the framework of biotechnology institutions has been established, it still requires improvement. Some important issues, such as biosafety, biodiversity, GMF, ethics, and genetic resources, have been noticed, yet a systemic institutional environment has not been formed, and detailed rules for implementation are required, e.g., the establishment of a national ethical review system. Therefore, there is an urgent need for the regulation of the ethics of biotechnology in China. The lack of regulations may result in two possible risks: Chinese researchers conduct biotechnology research at their will, and foreign researchers may conduct forbidden biotechnology research in China, which is prohibited in their country. Therefore, China is required to set up laws that protect gene information to clarify the ethical rules in R&D and the use of biotechnology.

Third, China is required to establish specific policies to implement the Biosecurity Law. In recent years, biotechnology safety has raised wide attention in China. In addition, the Biosecurity Law was finally put forward in 2020, setting basic rules, standards, and processes in dealing with biotechnology, yet specific measures have to be taken to implement the law.

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Appendix A. Main Government Documents of Biotechnology

Table A1. Law and other Policy Documents of National People's Congress.

Policy Document	Department
Biosecurity Law	National People's Congress, 2020
Outline of the 14th Five-Year Plan for National Economic and Social Development and the Vision for 2035	National People's Congress, 2021

Table A2. Policy Documents of the State Council.

Policy Document	Department
Opinions on Strengthening the Governance of S&T Ethics	General Office of the CPC Central Committee (GOCC), GOSC, 2022
Regulation on the Management of Human Genetic Resources. Order No. 717 of the State Council	State Council, 1986 (revised in 2019)
Opinions on Strengthening the Protection of Aquatic Organisms in the Yangtze River	GOSC, 2018
Regulation on the Biosafety Management of Pathogenic Microbe Labs. Order No. 424 of the State Council	State Council, 2004 (revised in 2016 and 2018)
Regulation on Administration of Safety of Agricultural Genetically Modified Organisms. Order No. 687 of the State Council	State Council, 2001 (revised in 2011 and 2017)

Table A2. *Cont.*

Policy Document	Department
Bio-Industry Development Plan. Guo Fa [2012] No. 65	State Council, 2012
Notice on Issuing the Several Policies in Promoting the Biology Industry Development. Guo Ban Fa [2009] No. 45	GOSC, 2009
11th Five-Year Plan of Biology Industry Development. Guo Ban Fa [2007] No. 23	GOSC, 2007
Opinions on Precaution of Alien Invasive Species	GOSC, 2003
List on Export of Dual-Use Biological Agents and Relative Equipment and Technology	State Council, 2002 (revised in 2006)
Outline of Action in protection of the Aquatic Organisms Resources	State Council, 2006
Mid-Long Term S&T Development Plan (2006–2020). Guo Fa [2005] No. 44	State Council, 2005
Notice on Strengthening the Protection and Administration of Biological Species Resource	GOSC, 2004
Critical Policy Points of Biotechnology Development. Guo Ban Fa [1988] No. 18	GOSC, 1988

Table A3. Policy Documents of the State Council departments.

Policy Document	Department
Management Measures on Safety of Biotechnology Research and Development. Guo Ke Fa She [2017] No. 198	MOST, 2017
13th Five-Year Plan of Biotechnological Innovation. Guo Ke Fa She [2017] No. 103	MOST, 2017
13th Five-Year Plan on Biology Industry Development. Fa Gai Gao Ji [2016] No. 2665	NDRC, 2016
Building Plan of High-Level Biosafety Laboratory System (2016–2025)	NDRC and MOST, 2016
13th Five-Year Plan of Biomass Energy Development	NEA, 2016
Measures for the Ethical Review of Biomedical Research Involving Humans. Order No. 11 of NHC	National Health and Family Planning Commission (NHFPC, presently NHC), 2007 (revised in 2016)
Development Policies for the Biodiesel Industry	NEA, 2014
Development Plan on National Forest Biomass Energy (2011–2020)	State Forestry Administration (SFA, present NFGB), 2013
12th Five-Year Plan of Biomass Energy	NEA, 2012
National Mid-Long Term Biotechnology Talent Development Plan (2010–2020). Guo Ke Fa She [2011] No. 673, 2011	MOST, 2011
12th Five-Year Plan of Biotechnology Development. Guo Ke Fa She [2011] No. 588	MOST, 2011
Urgent Notice on strengthening the Administration of Research on Highly Pathogenic Microorganisms	Ministry of Agriculture (MOA, presently MARA), 2005
Method on Administration of Genetic Engineering Safety	State Scientific and Technological Commission (SSTC, presently MOST), 1993

References

1. Commission of the European Communities. Preparing for Our Future: Developing a Common Strategy for Key Enabling Technologies in the EU. 2009. Available online: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A52009DC0512 (accessed on 2 April 2022).
2. OECD. *A Framework for Biotechnology Statistics*; OECD: Paris, France, 2005.
3. Zilberman, D.; Kim, E.; Kirschner, S.; Kaplan, S.; Reeves, J. Technology and the Future Bioeconomy. *Agric. Econ.* **2013**, *44*, 95–102. [CrossRef]
4. El-Chichakli, B.; von Braun, J.; Lang, C.; Barben, D.; Philp, J. Policy: Five Cornerstones of a Global Bioeconomy. *Nature* **2016**, *535*, 221–223. [CrossRef] [PubMed]
5. Bugge, M.M.; Hansen, T.; Klitkou, A. What Is the Bioeconomy? A Review of the Literature. *Sustainability* **2016**, *8*, 691. [CrossRef]
6. Rabitz, F. Institutional Drift in International Biotechnology Regulation. *Glob. Policy* **2019**, *10*, 227–237. [CrossRef]
7. McCormick, K.; Kautto, N. The Bioeconomy in Europe: An Overview. *Sustainability* **2013**, *5*, 2589–2608. [CrossRef]
8. Arujanan, M.; Singaram, M. The Biotechnology and Bioeconomy Landscape in Malaysia. *New Biotechnol.* **2018**, *40*, 52–59. [CrossRef]
9. Wiktorowicz, M.; Deber, R. Regulating Biotechnology: A Rational-Political Model of Policy Development. *Health Policy* **1997**, *40*, 115–138. [CrossRef]
10. Cyranoski, D.; Ledford, H. Genome-Edited Baby Claim Provokes International Outcry. *Nature* **2018**, *563*, 607–608. [CrossRef]
11. Cohen, J. Did CRISPR Help—or Harm—the First-Ever Gene-Edited Babies? *Science* **2019**, *21*. [CrossRef]
12. Lee, J.; Wang, F. Gene-Edited Baby by Chinese Scientist: The Opener of the Pandora's Box. *Sci. Insigt* **2018**, *2018*, e000178. [CrossRef]
13. Cyranoski, D. What CRISPR-Baby Prison Sentences Mean for Research. *Nature* **2020**, *577*, 154–155. [CrossRef] [PubMed]
14. Chen, Z.; Guan, J. Mapping of Biotechnology Patents of China from 1995–2008. *Scientometrics* **2011**, *88*, 73–89. [CrossRef]
15. van Dongen, P.; Tak, H.; Claassen, E. Policies and Patenting to Stimulate the Biotechnology Sector: Evidence from The Netherlands. *Sci. Public Policy* **2019**, *46*, 136–147. [CrossRef]
16. Bronzini, R.; Piselli, P. The Impact of R&D Subsidies on Firm Innovation. *Res. Policy* **2016**, *45*, 442–457. [CrossRef]
17. Geuna, A.; Rossi, F. Changes to University IPR Regulations in Europe and the Impact on Academic Patenting. *Res. Policy* **2011**, *40*, 1068–1076. [CrossRef]
18. Henderson, R.; Jaffe, A.B.; Trajtenberg, M. Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965–1988. *Rev. Econ. Stat.* **1998**, *80*, 119–127. [CrossRef]
19. Arundel, A. *Biotechnology Indicators and Public Policy*; OECD Science, Technology and Industry Working Papers; OECD Publications: Paris, France, 2003; Volume 2003/05.
20. Aghmiuni, S.K.; Siyal, S.; Wang, Q.; Duan, Y. Assessment of Factors Affecting Innovation Policy in Biotechnology. *J. Innov. Knowl.* **2020**, *5*, 180–190. [CrossRef]
21. Wang, R.; Cao, Q.; Zhao, Q.; Li, Y. Bioindustry in China: An Overview and Perspective. *New Biotechnol.* **2018**, *40*, 46–51. [CrossRef]
22. Stewart, P.A.; Knight, A.J. Trends Affecting the next Generation of U.S. Agricultural Biotechnology: Politics, Policy, and Plant-Made Pharmaceuticals. *Technol. Forecast. Soc. Chang.* **2005**, *72*, 521–534. [CrossRef]
23. Zhang, F.; Cooke, P.; Wu, F. State-Sponsored Research and Development: A Case Study of China's Biotechnology. *Reg. Stud.* **2011**, *45*, 575–595. [CrossRef]
24. Murmann, J.P. *Knowledge and Competitive Advantage: The Coevolution of Firms, Technology, and National Institutions*; Cambridge University Press: Cambridge, UK, 2003.
25. Nelson, R.R. The Co-Evolution of Technology, Industrial Structure, and Supporting Institutions. *Ind. Corp. Chang.* **1994**, *3*, 47–63. [CrossRef]
26. Dietz, T.; Börner, J.; Förster, J.; von Braun, J. Governance of the Bioeconomy: A Global Comparative Study of National Bioeconomy Strategies. *Sustainability* **2018**, *10*, 3190. [CrossRef]
27. Peng, M.W.; Sun, S.L.; Pinkham, B.; Chen, H. The Institution-Based View as a Third Leg for a Strategy Tripod. *Acad. Manag. Perspect.* **2009**, *23*, 63–81. [CrossRef]
28. Oliver, C. Sustainable Competitive Advantage: Combining Institutional and Resource-Based Views. *Strateg. Manag. J.* **1997**, *18*, 697–713. [CrossRef]
29. Peng, M.W. Towards an Institution-Based View of Business Strategy. *Asia Pac. J. Manag.* **2002**, *19*, 251–267. [CrossRef]
30. Peng, M.W.; Ahlstrom, D.; Carraher, S.M.; Shi, W. An Institution-Based View of Global IPR History. *J. Int. Bus. Stud.* **2017**, *48*, 893–907. [CrossRef]
31. Freeman, R.E. *Strategic Management: A Stakeholder Approach*; Cambridge University Press: Boston, MA, USA, 1984.
32. Buchholz, R.A.; Rosenthal, S.B. Stakeholder Theory and Public Policy: How Governments Matter. *J. Bus. Ethics* **2004**, *51*, 143–153. [CrossRef]
33. Loureiro, S.M.C.; Romero, J.; Bilro, R.G. Stakeholder Engagement in Co-Creation Processes for Innovation: A Systematic Literature Review and Case Study. *J. Bus. Res.* **2020**, *119*, 388–409. [CrossRef]

34. Crilly, D.; Zollo, M.; Hansen, M.T. Faking It or Muddling Through? Understanding Decoupling in Response to Stakeholder Pressures. *Acad. Manag. J.* **2012**, *55*, 1429–1448. [CrossRef]
35. Parmar, B.L.; Freeman, R.E.; Harrison, J.S.; Wicks, A.C.; Purnell, L.; de Colle, S. Stakeholder Theory: The State of the Art. *Annals* **2010**, *4*, 403–445. [CrossRef]
36. Laplume, A.O.; Sonpar, K.; Litz, R.A. Stakeholder Theory: Reviewing a Theory That Moves Us. *J. Manag.* **2008**, *34*, 1152–1189. [CrossRef]
37. Yunan, X.; Weixin, L.; Yujie, Y.; Hui, W. Evolutionary Game for the Stakeholders in Livestock Pollution Control Based on Circular Economy. *J. Clean. Prod.* **2021**, *282*, 125403. [CrossRef]
38. Prud'homme, D.; Tong, T.W.; Han, N. A Stakeholder-Based View of the Evolution of Intellectual Property Institutions. *J. Int. Bus. Stud.* **2021**, *52*, 773–802. [CrossRef]
39. Bingham, L.B.; Nabatchi, T.; O'Leary, R. The New Governance: Practices and Processes for Stakeholder and Citizen Participation in the Work of Government. *Public Adm. Rev.* **2005**, *65*, 547–558. [CrossRef]
40. Carroll, A.B. *Business & Society: Ethics and Stakeholder Management*, 3rd ed.; Cengage Learning, Inc.: Cincinnati, OH, USA, 1996.
41. Donaldson, T.; Preston, L.E. The Stakeholder Theory of the Corporation: Concepts, Evidence, and Implications. *Acad. Manag. Rev.* **1995**, *20*, 65–91. [CrossRef]
42. Yin, R.K. *Case Study Research: Design and Methods*, 3rd ed.; Sage Publications: Thousand Oaks, CA, USA, 2003.
43. Siggelkow, N. Persuasion With Case Studies. *Acad. Manag. J.* **2007**, *50*, 20–24. [CrossRef]
44. Ahuja, G.; Katila, R. Technological Acquisitions and the Innovation Performance of Acquiring Firms: A Longitudinal Study. *Strateg. Manag. J.* **2001**, *22*, 197–220. [CrossRef]
45. Carree, M.; Piergiovanni, R.; Santarelli, E.; Verheul, I. Factors Favoring Innovation from a Regional Perspective: A Comparison of Patents and Trademarks. *Int. Entrep. Manag. J.* **2015**, *11*, 793–810. [CrossRef]
46. Van Beuzekom, B.; Arundel, A. *OECD Biotechnology Statistics-2009*; OECD: Paris, France, 2009.
47. Friedrichs, S.; van Beuzekom, B. *Revised Proposal for the Revision of the Statistical Definitions of Biotechnology and Nanotechnology*; OECD Science, Technology and Industry Working Papers; OECD Publishing: Paris, France, 2018; Volume 1.
48. North, D. *Institutions, Institutional Change, and Economic Performance*; Harvard University Press: Cambridge, UK, 1990.
49. Di, Y.; Chen, R. A Brief Introduction of the National Laboratory and National Key Laboratory. *Mod. Sci.* **2019**, *7*, 24–33. (In Chinese)
50. Xu, K.; Sun, L. Development Status and Problems of Biomedical Industrial Parks in China. *Chin. J. New Drugs* **2019**, *28*, 2440–2446.
51. Keupp, M.M.; Friesike, S.; von Zedtwitz, M. How Do Foreign Firms Patent in Emerging Economies with Weak Appropriability Regimes? Archetypes and Motives. *Res. Policy* **2012**, *41*, 1422–1439. [CrossRef]
52. Teferra, T.F. Should We Still Worry about the Safety of GMO Foods? Why and Why Not? A Review. *Food Sci. Nutr.* **2021**, *9*, 5324–5331. [CrossRef] [PubMed]
53. Kou, J.; Tang, Q.; Zhang, X. Agricultural GMO Safety Administration in China. *J. Integr. Agric.* **2015**, *14*, 2157–2165. [CrossRef]
54. Sili, M.; Dürr, J. Bioeconomic Entrepreneurship and Key Factors of Development: Lessons from Argentina. *Sustainability* **2022**, *14*, 2447. [CrossRef]
55. Lokko, Y.; Heijde, M.; Schebesta, K.; Scholtès, P.; Van Montagu, M.; Giacca, M. Biotechnology and the Bioeconomy—Towards Inclusive and Sustainable Industrial Development. *New Biotechnol.* **2018**, *40*, 5–10. [CrossRef] [PubMed]
56. Linstone, H.A. Technology and Governance: An Introduction. *Technol. Forecast. Soc. Chang.* **1997**, *54*, 1–10. [CrossRef]
57. Raybould, A. New Frontiers in Biosafety and Biosecurity. *Front. Bioeng. Biotechnol.* **2021**, *9*, 657. [CrossRef]
58. van Oudheusden, M. Where Are the Politics in Responsible Innovation? European Governance, Technology Assessments, and Beyond. *J. Responsible Innov.* **2014**, *1*, 67–86. [CrossRef]
59. Marchant, G.E.; Wallach, W. Coordinating Technology Governance. *Issues Sci. Technol.* **2015**, *31*, 43–50.
60. Fosch-Villaronga, E.; Heldeweg, M. "Regulation, I Presume?" Said the Robot—Towards an Iterative Regulatory Process for Robot Governance. *Comput. Law Secur. Rev.* **2018**, *34*, 1258–1277. [CrossRef]
61. Böhme, R.; Christin, N.; Edelman, B.; Moore, T. Bitcoin: Economics, Technology, and Governance. *J. Econ. Perspect.* **2015**, *29*, 213–238. [CrossRef]
62. Qianqian, G.; Jinjin, W. Legal Prevention of Biotechnology Risks from the Perspective of COVID-19 Pandemic. *Sci. Technol. Law* **2021**, *1*, 140–148.
63. Xue, Y.; Yu, H.; Qin, G. Towards Good Governance on Dual-Use Biotechnology for Global Sustainable Development. *Sustainability* **2021**, *13*, 14056. [CrossRef]
64. de Graeff, N.; Dijkman, L.E.; Jongsma, K.R.; Bredenoord, A.L. Fair Governance of Biotechnology: Patents, Private Governance, and Procedural Justice. *Am. J. Bioeth.* **2018**, *18*, 57–59. [CrossRef]
65. Smyth, S.J.; Wesseler, J. The Future of Genome Editing Innovations in the EU. *Trends Biotechnol.* **2022**, *40*, 1–3. [CrossRef] [PubMed]
66. Eriksson, D.; Custers, R.; Edvardsson Björnberg, K.; Hansson, S.O.; Purnhagen, K.; Qaim, M.; Romeis, J.; Schiemann, J.; Schleissing, S.; Tosun, J.; et al. Options to Reform the European Union Legislation on GMOs: Scope and Definitions. *Trends Biotechnol.* **2020**, *38*, 231–234. [CrossRef] [PubMed]
67. Yu, H.; Taduri, S.; Kesan, J.; Lau, G.; Law, K.H. Mining Information across Multiple Domains: A Case Study of Application to Patent Laws and Regulations in Biotechnology. *Gov. Inf. Q.* **2012**, *29*, S11–S21. [CrossRef]

68. Kuzma, J. A Missed Opportunity for U.S. Biotechnology Regulation. *Science* **2016**, *353*, 1211–1213. [CrossRef]
69. Sheldon, I.M. Regulation of Biotechnology: Will We Ever 'Freely' Trade GMOs? *Eur. Rev. Agric. Econ.* **2002**, *29*, 155–176. [CrossRef]
70. Karky, R.B. Japanese Biotechnology Regulation and Life Science (Gene) Patenting. *J. World Intellect. Prop.* **2021**, *24*, 404–419. [CrossRef]