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RESEARCH ARTICLE

Trends in herbal pharmaceutical patent protection for Dairy industry: Perspective from Grassroots innovations

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Abstract: The national patent regime had amended Patent Act on innovation as per requirement for protecting pharmaceutical product patents among member states of World Trade Organisation. In this respect, the study was conducted to understand patentability nature and prosecution timelines for patent protected indigenous dairy technologies. Investigators had examined 28 herbal pharmaceutical patent grant(s) from grassroots innovators/outstanding knowledge holders. Patent applications were filed between 2007-2014, prosecution were held and accorded patent grant during 2019-2022. The study noted that Section 3 (d), (e) and (p) were principal factors involved while defending veterinary pharmaceutical patent applications. About 46 percent did not have Section 3 (d) objections inferring these medicinal practices followed by dairy farmers were unique. It was observed that majority of patent grants were in product category illustrating transformation of national patent regime from process patent to product-patent grant system. Overall time taken for availing grant was about ten years with an average prosecution period of 2.6 years. Therapeutic efficacy, synergistic action and suitable claim amendments are pertinent features in responding to prosecution stages. These pharmaceutical product patents from social innovation are of interest to dairy industry. These experimental wisdom provide cost effective sustainable technologies for dairy health system and repurpose existing knowledge of local communities. It is paramount to nurture this bottom-up approach for improvising sustainable dairy health service delivery system.

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Introduction

The contribution of outstanding knowledge practices from societal experimentation to dairy health care and production system were recognized (Eiki et al. 2021). There is appreciation of usefulness indigenous knowledge systems, however limited literature were available on their innovation capabilities, protection through patent filing. These new knowledge are key for focussed goals in socio economic development and drivers for industrial growth. Innovation is endogenous to economic progress (Kaplinsky and Mbula, 2022; Singh et al. 2015). Emerging economies like India had society comprising largely informal sector contributing to innovation-economic paradigm. With large pool of informal economy, India had pioneered in recognizing innovative ability of individuals who were not part of formal system (Ustyuzhantseva, 2015).These social innovations were considered as an outcome to overcome limitations in routine activities. Efforts to strengthen this bottom-up approach had created attention among rural region (Ferreiro et al. 2021).These innovations are developed to combat existing problem and for creating new opportunity (Taalbi, 2017). The need to involve multiple process in iterative innovation system is essential to address societal requirements and for seizing opportunities (Poblete et al. 2022). India is among the top three innovation economies of Central and Southern Asia region and ranked 40 in Global Innovation Index. The country positioned first among lower middle-income group of nations (GII, 2022).

Sustainable Development Goals 2030 of United Nations require dairy sector to embrace greener technologies (Granato et al. 2022). These are crucial development for dairy sector, which needs to access new medications with less cost involvement. Herbal medicines play vital role in dairy sector and it is necessary to examine requirements in protecting indigenous knowledge system through pharmaceutical grants. Strengthening these social innovations will be key to support dairy health systems (Ravikumar et al. 2017). The need for supporting local entrepreneurial activity at early stages in development of

technology and practices of community is felt (Cuntz and Peuckert, 2023). A strong Intellectual Property Rights (IPR) protection regime and their joint effect are positively associated with technology adoption (Jayasekara and Fredriksson, 2021).The patent filing rate had grown to 1.6 percent compared to 2019 (Bhardwaj and Arora, 2023) and increasing patent filing activity can attract industries enabling largescale commercial diffusion.

Inorder to meet this purpose, Intellectual Property Rights policies had evolved since entry of India into Trade related aspects of Intellectual Property Rights (TRIPS) through amendment of Patent Act. This engagement was heldbased on sensitization of protecting community practices that otherwise had taken longer prosecution stages to defend *eg*., Turmeric patent (Mashelkar, 2001). Accordingly, national IPR system started permitting pharmaceutical patent grants for *process claim* thereby ensured accessibility of cost effective medicines. Since 1972-2004, pharmaceutical industry in India relied on process-patent system (Haley and Haely, 2012). There is need to introduce product patent grants for scaling up accessibility of medicines. Amendments like Section 3 (d) of Indian Patent Act was introduced by 2005 that led to examination of pharmaceutical patent applications both for process and product claim(s).This Section 3 (d) reiterated 'significant enhanced efficacy of a known substance 'towards clearance of pharmaceutical patent grant.

Patent applications need to disclose appropriate information that establishes novelty, suitable inventive steps, and usefulness in terms of industrial application (Blind et al. 2022). Moreover, disclosure needs to be "sufficiently clear and complete to enable it to be replicated by a person with an ordinary level of skill in the relevant technical field" as per patent office. Industries had adequate attention for protection of herbal products through patent claims. The volume of Indian Pharmaceutical Industry is third largest in the world and thirteenth in value producer (Singh, 2022). This reiterates need for critical engagement in development of herbal drugs, meet with global changes. Indian national patent system had considered these priorities and with several policy changes, IPR policy was adopted in May 2016 [GoI, 2021]. It is to be noted that only 40 percent of innovative technologies developed were transformed into application in developing world, which is 70-85 percent in developed world (Wu and Li 2023). The innovation performances need to be reinforced by innovation policies and appropriate practices for desirable outcome.

Hence, it is necessary to understand emerging trends on herbal pharmaceutical patent prosecution governed by national IPR jurisdiction. The study examined herbal pharmaceutical patents in light change in IPR policies for upscaling domestic innovation system. This insight can help to understand, develop suitable technological approach for dairy industry and to explore necessary practices in harnessing social innovation derived from grassroots/outstanding herbal practices.

Methodology

The study had examined 28 patent grants accorded by Indian Patent Office [IPO] in the field of dairy sector. These patent applications were enlisted based on the grant availed during 2019-2022 by National Innovation Foundation-India [NIF]. The priority date of examined applications were between 2007-2014 and filed from 9 states of India [Table 1, 2]. The investigation had examined the nature of Section 3 objections raised by IPO during prosecution stages of these applications. Investigators were part of correspondence between applicants and patent office in terms of responding to First Examination Report's, Controller reports and hearing/prosecution process. The study also assessed time duration during prosecution period and from priority date of filing for these herbal pharmaceutical grants. Nature of claim amendment(s) and issuance of patent grant based on process or product or both were recorded.

Results and Discussion

These herbal veterinary pharmaceutical patent grants were received for grassroots innovator(s) being incubated by National Innovation Foundation-India. A total of 28 veterinary patent grants were received for green grassroots innovators located from 9 states of the country. These patent rights are crucial for recognizing innovation capabilities of knowledge holder(s)from informal society. Such development can assist in scaling up of social innovation through commercial sphere. These activities distinguished knowledge holders based on technological practice(s) shared by them and confirmed prevalence of novel/ unique medicinal systems, being practiced at farming communities. Intellectual property rights protection is an essential step in commercial product cycle facilitating licensing agreements.

Nature of Section 3 objections

Indian IPR regime had to comply with TRIPS and introduced Section 3 (d). The section examines patentability in terms of mere 'discovery new form of known substance', 'discovery of new use of known substance' and 'mere use of known process'. The study had identified 15 of these grants which had at least Section 3 (d) objections in First Examination Report [FER]. The patentability nature of such applications were put forth by demonstrating significantly enhanced efficacy. Remaining 13 patent grants (46 percent) were not known earlier and reflecting unique dairy technologies. It is pertinent to protect these indigenous herbal wisdom maintained at different geographical communities. Knowledge holders had sustained not only the knowledge of unique herbal medicine but also capability of utilization of practice to address complex dairy health constraints. These innovations are endogenous in nature. Necessary support system can enhance capability to assimilate new information.

Table 1: Prosecution information

Ailment	State	Application Number	Priority date	Date of Grant	Date of FER Response Filed	Nature of Section 3 objections
Ephemeral Fever	Himachal Pradesh	3188/DEL/2012	12-10-2012	31-10-2022	23-08-2019	(c), (d), (i),(j), (p)
Milk Yield	Odisha	1453/KOL/2012	24-12-2012	13-09-2022	24-06-2020	(e) , (i)
Expulsion Of Placenta	Gujarat	1049/MUM/2011	31-03-2011	09-09-2022	11-10-2016	(e)
Mastitis	Tamil Nadu	998/CHE/2014	27-02-2014	30-06-2022	27-06-2019	(d), (e), (p)
Herbal formulation for the treatment or prevention of mastitis	Gujarat	3754/MUM/2014	26-11-2014	30-05-2022	26-12-2019	(p), (d), (e)
Bloat	Gujarat	1115/MUM/2011	31-03-2011	12-04-2022	21-12-2018	(p), (e)
Endoparasitic Infections	Odisha	486/KOL/2011	04-04-2011	30-03-2022	08-06-2019	(c), (e), (j),(p)
Estrus In Animals	Gujarat	1109/MUM/2011	31-03-2011	24-02-2022	19-12-2018	(p), (e)
Anestrus In Animals	Odisha	489/KOL/2011	04-04-2011	21-01-2022	5-12-2019	(d), (i), (p)
Bloat	Bihar	449/KOL/2011	31-03-2011	07-10-2021	19-12-2018	(p), (e)
Estrus In Animal	Gujarat	1114/MUM/2011	31-03-2011	07-10-2021	20-12-2018	(p), (e)
Ectoparasitic Infestation	Tamil Nadu	1039/CHE/2011	31-03-2011	06-10-2021	28-05-2019	(c),(d)(e), (j), (p)
Gastrointestinal disorders	Odisha	467/KOL/2011	01-04-2011	05-10-2021	30-04-2019	(d),(e), 3(p)
Fever Treatment In Animals	Tamil Nadu	1111/CHE/2011	01-04-2011	17-09-2021	25-02-2019	(d),(e),(i),(p)
Bloat	Gujarat	202/MUM/2007	05-02-2007	26-08-2021	23-10-2013	(e)
Bloat	Tamil Nadu	1011/CHE/2011	30-03-2011	07-07-2021	28-03-2019	(d), (e), (i), (p)
Mastitis	Tamil Nadu	1113/CHE/2011	01-04-2011	06-07-2021	15-02-2019	(d), (e), (i), (p)
Milk Yield In Cattle	Gujarat	1028/MUM/2011	31-03-2013	05-07-2021	09-04-2019	(d), (e), (p)

Table 2: Nature of patent grants and timelines

Application Number	Composition or Single Herb	Claim Amendment(s)	Product/ process or both	Time duration during prosecution stage (Days)	Time duration to obtain grant since priority date [Days]
3188/DEL/2012	Composition	Principal claim amended	Product	1165	3671
1453/KOL/2012	Composition	Principal claim amended	Product & Process	812	3550
1049/MUM/2011	Composition	Principal claim amended	Product & Process	2159	4180
998/CHE/2014	Composition	Principal claim amended	Product & Process	1099	3045
3754/MUM/2014	Composition	Principal claim amended	Product & Process	886	2742
1115/MUM/2011	Composition	Principal claim amended	Product	1208	4013
486/KOL/2011	Composition	Principal claim amended	Product & Process	1026	4016
1109/MUM/2011	Composition	Principal claim amended	Product & Process	1163	3983
489/KOL/2011	Composition	No change in Principal claim	Product & Process	778	3945
449/KOL/2011	Composition	Principal claim amended	Product & Process	1023	3843
1114/MUM/2011	Composition	Principal claim amended	Product & Process	1022	3843
1039/CHE/2011	Composition	Principal claim amended	Product & Process	862	3842
467/KOL/2011	Composition	Principal claim deleted	Process	889	3840
1111/CHE/2011	Composition	Principal claim amended	Product & Process	935	3822
202/MUM/2007	Composition	No change in Principal claim	Process	2864	5316
1011/CHE/2011	Composition	Principal claim amended	Product & Process	832	3752
1113/CHE/2011	Composition	Principal claim amended	Product & Process	872	3749
1028/MUM/2011	Composition	No change in the claims	Product & Process	818	3749
1027/MUM/2011	Composition	Principal claim deleted	Process	775	3661
999/CHE/2014	Composition	Principal claim amended	Product & Process	442	2582
2243/CHE/2008	Composition	Principal claim amended	Product & Process	696	4569
997/CHE/2014	Single	Principal claim amended	Product & Process	562	2521
463/KOL/2011	Composition	Principal claim amended	Product & Process	685	3559
1053/MUM/2011	Composition	Principal claim amended	Product & Process	1061	3492
562/KOL/2012	Composition	Principal claim amended	Product & Process	373	3076
648/KOL/2012	Composition	Principal claim amended	Product & Process	675	2663
1051/MUM/2011	Composition	Principal claim amended	Product & Process	419	3080
1033/CHE/2011	Composition	Principal claim amended	Product & Process	371	3039

Twenty patent applications (89 percent) had objections on the ground of Section 3 (e) referring herbal compositions were mere admixture. Except one applications, rest of 27 granted application are in the form of herbal composition. Therapeutic value along with features were illustrated and necessary claim amendment(s) were carried out in overcoming objections for according pharmaceutical grants. FER examination of these applications indicated about 82 percent (23 grants) had Section (p) objections referring as Traditional knowledge. Traditional knowledge cannot be protected with patent system as it is known for generation. Further, Indian Patent system did not allow patent grant on the basis of mere aggregations or duplication of known properties. This was due to plant biodiversity and associated knowledge being maintained at local communities. These knowledge is known and available as prior art and measures to prevent unfair exploitation

In general, these applications have to ensure sufficiency of disclosure interms of working examples, differentiating features of composition through prior art and experimentation to prove these practices are effective. The distinguishing nature of herbal compositions were elaborated during prosecution stage and grants were accorded.

Claim amendment(s) on process and product patent grant

It was noted that for 23 grants received had principal claim amendment(s). The prosecution proceedings had resulted about 82 percent of grants (n=23 grants) as product and process pharmaceutical grants. It was also noted that two applications (n=2) were accorded with product grants. It is essential to protect original product during early stage of Research and Development process. This only provide incentive to industry as it enables exclusivity in the market. Overall only 10 percent (3 applications) of these dairy knowledge applications had resulted in process grant. In access to drugs, India had restricted product patent grant before embarking into WTO (Pre TRIPS) in order to avoid monopoly of drugs. Agreement on Trade related aspects of Intellectual Property Rights (TRIPS) of World Trade Organization had mandated members in protecting patents on pharmaceutical products (Dai and Watal, 2021). Subsequently, the IP system had evolved to meet the international obligations.The study had found that with changes in patent laws, decisions were oriented product patent grant(s). This augments well for domestic innovation system.

Social innovations for dairy health and production

Technologies related to dairy *viz*., ephemeral fever, expulsion of placenta, anestrus, mastitis, bloat, endoparasite, ectoparasite, enteritis and nutritional supplements for milk yield were protected based on societal wisdom at IPO. These technological practices had evolved from experimental nature of dairy farming communities to sustain dairy health production and welfare.

The studies found that majority of patent grants were in product category and directly related to serve the purpose of claim. This provides critical insight to understand social realities in terms of contribution of informal knowledge system in sustainable rural dairy health system. Systemic adaptation to contextual aspects can help in nurturing technological and innovation capabilities (Mugwagma et al. 2022). Knowledge holders had minimized distress of dairy communities and reduced input cost in treatment of mastitis to the tune of Rs. 1800 per animal (Devgania et al. 2015). The compliance with patent legislation provide impetus to these technologies in value chain. IPR are vital during development stage of a medication from conception stage to product. These patent protected technologies can aid in development of new products and minimize factors affecting innovation performance. Innovation waves can happen with support of social transformation, complementary conditions, longer duration, availability of radical innovation and mass production (GII, 2022).The interface of indigenous knowledge with service institutions where farmers largely rely was stressed (Thakur et al. 2022). Sustained efforts are needed to realise potential of technologies into scalable innovation in market place.

Prosecution duration for herbal pharmaceutical applications

Investigators had evaluated prosecution record(s) of each of these 28 pharmaceutical patent grants. As per WTO requirement, developing countries evolved towards open economies and tries to adapt their patent systems (Vu, 2012). Applications have to meet requirements of Access and Benefit Sharing [ABS] agreement as per Biodiversity Act 2002 to receive IPO clearance. The regulation based on Convention on Biological Diversity [CBD] in seeking mutually agreed agreement for equitable benefit sharing upon utilization of material were adhered from knowledge holders. These obligations were based on Nagoya protocol, a supplementary agreement under CBD on ABS implemented from 12th October 2014 (Davis et al. 2015). The study noted that average time duration during prosecution stage was945 days [approximately 2.62 years or31 months]. It had taken on an average 3612 days [approximately 10 years/120 months] to accord patent grant from the date of priority. This empirical contribution is essential for scope of filing patent and appropriability of wisdom.

Conclusion

Herbal practices are the immediate access points for health care system especially in dairy sector. The study had provided insights on innovation capabilities of green grassroots innovators based on 28 patent grants. A total of 13 patents were granted in North; Western regions; 13 patent grants were in Southern regions and 2 patent grants in North Eastern regions of the country. These were from larger geographical regions of the country illustrating complementing role of grassroots innovators in dairy production system.Upon examination of pharmaceutical patent grants it was noted that Section 3 (d), 3 (e) and 3 (p) as major objections during

prosecution stages. Claim analysis indicated that most of these grants had novel poly herbal composition. It also highlighted the changed direction of patent regime moving towards product patent system thereby augmenting domestic innovation(s). The study-reinforced bottom up approach in incubating social innovation and protection of unique technologies may help in accessing new knowledge by dairy enterprises.

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References

Bharadwaj M, Arora S (2023) Innovators in India need to gear up for filing more patents, Current Sci 124:147-148

Blind K, Krieger B, MaikelPellens (2022) The interplay between product innovation, publishing, patenting and developing standards. Research Policy 51. 104556.https://doi.org/10.1016/j.respol.2022.104556

Cuntz A, Peuckert J (2023) From hackers to start-ups: Innovation commons and local entrepreneurial activity, Research Policy 52:2 104675.https://doi.org/10.1016/j.respol.2022.104675

Dai R, Watal J (2021) Product patents and access to innovative medicines. Social Sci Med 291: 114479. https://doi.org/10.1016/j.socscimed.2021.114479

Davis K, Smit MF, Kidd M, Sharrock S, Allenstein P (2015) An access and benefit sharing awareness survey for botanic gardens: Are they prepared for the Nagoya protocol? South African J Botany 98:148-156. doi : 10.1016/j.sajb.2015.01.015

Devgania BS, Khordia D, Chodvadiya MB, Patel R, Patel D, Kinhekar AS, Singh PK, Kumar V, Bhojne GR, Ravikumar RK, Kumar V (2015) Reverenceof community towards grassroot livestock innovation: Responding to stakeholders need against sub-clinical mastitis in Amreli District, Gujarat, India. Adv Anim Vet Sci 3: 689-693.DOI | http://dx.doi.org/10.14737/journal.aavs/2015/3.12.689.693

Eiki N, Sebola NA , Sakong BM, Mabelebele M (2021) Review on Ethnoveterinary Practices in Sub-Saharan Africa. Vet Sci 8:99.https://doi.org/10.3390/vetsci8060099

Ferreiro AF, Sousa C, Sheikh FA, Novikova M (2021) Social innovation and rural territories: Exploring invisible contexts and actors in Portugal and India, J Rural Stud https://doi.org/10.1016/j.jrurstud.2021.04.013

GII (2022) Global Innovation Index 2022. What is the future of innovation driven growth? 15th edition, World Intellectual Property Organization 34, chemin des Colombettes, P.O. Box 18 CH-1211 Geneva 20, Switzerland

GoI (2021) Review of the Intellectual Property Rights Regime in India, 161 Report, Department Related Parliamentary Standing Committee On Commerce, Parliament of India, Rajya Sabha Secretariat, New Delhi

Granato D, Carocho M, Barros L, Zabetakis I, Mocan A, Tsoupras A, Cruz AG, Pimentel TC (2022) Implementation of Sustainable Development Goals in the dairy sector: Perspectives on the use of agro-industrial side-streams to design functional foods. Trends Food Sci Technol 124:128-139. https://doi.org/10.1016/j.tifs.2022.04.009

Haley GT, Haely UCV (2012) The effects of patent-law changes on innovation: The case of India's pharmaceutical industry. Technol Forecasting Social Change 79: 607-619.DOI:10.1016/j.techfore.2011.05.012

Jayasekara DN, Fredriksson PG (2021) Culture, Intellectual property rights and technology adoption. Quarterly Rev Econ Finance, 80:317-330. https://doi.org/10.1016/j.qref.2021.03.007

Kaplinsky R, Kraemer-Mbula E (2022) Innovation and uneven development: The challenge for low- and middle-income economies. Research Policy 51:2 https://doi.org/10.1016/j.respol.2021.104394.

Mashelkar RA (2001) Intellectual property rights and the Third world. Special section: Science in the third world. Current Sci 81: 955-965

Mugwagwa J, Banda G, Ozor N, Bolo M, Oriama R (2022) Optimising governance capabilities for science, research and innovation in Africa. Technol Society 68, . https://doi.org/10.1016/j.techsoc.2021.101804

Poblete L, Kadefors A, Radberg KK, Gluch P (2022) Temporality, temporariness and keystone actor capabilities in innovation ecosystems. Industrial Marketing Manag 102. https://doi.org/10.1016/j.indmarman.2022.01.012

Ravikumar RK, Thakur D, Choudhary H, Kumar V, Kinhekar AS, Garg T, Ponnusamy K, Bhojne GR, Shetty VM, Kumar V (2017). Social engineering of societal knowledge in livestock science: Can we be more empathetic? Vet World 10: 86-91

Singh K (2022) Impact of Patent (Amendment) Act, 2005 on Indian Pharmaceutical Industry. J Intellectual Property Rights 27: 397-414, doi: 10.56042/jipr.v27i6.63793

Singh V, Kumar P, Datt S, Ponnusamy K (2015) Intellectual assets management and transfer in animal science sector at the Indian Council of Agricultural Research (ICAR). Indian J Anim Sci 85: 1051–1055

Taalbi J (2017) What drives innovation? Evidence from economic history, Research Policy, 46:1437-1453.https://doi.org/10.1016/j.respol.2017.06.007

Thakur D, Dinesh K, Sharma M, Ravikumar RK, Masand R, Sharma D (2022). Tick control management practices of dairy farmers in Kangra district of Himachal Pradesh, India, Indian Journal of Dairy Science, 75(4): 388-391. https://doi.org/10.33785/IJDS.2022.v75i04.013

Ustyuzhantseva (2015) Institutionalization of grassroots innovation in India, Current Science, 108 (8): 1476- 1482

Vu TA (2012) An insight into the patent systems of fast developing ASEAN countries, World Patent Information, 34(2): 134-142,https://doi.org/10.1016/j.wpi.2011.12.007

Wu H, Li J(2023) Risk preference, interlinked credit and insurance contract and agricultural innovative technology adoption, Journal of Innovation & Knowledge, 8: 1, January–March 2023, 100282,https://doi.org/10.1016/j.jik.2022.100282