RESEARCH PAPER

Blood Patentability in Question: The Purview of Intellectual Property Law

Dr. Plabita Saikia[1*]

[1*]Assistant Professor (Law), Dispur Law College, Dispur, Guwahati, Assam (India) Pin-781006

Email: plabitas30@gmail.com

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ABSTRACT

The National Health Policy, 2002, directed the State to commit to universal health care through a "realistic" consideration of capacity (infrastructure and resources) as a key challenge toward making health care available to all. Within the human body, blood performs two primary functions in transportation of oxygen to various tissues and removal of carbon dioxide from the body. For considerable time, human kind is facing the problem of blood shortage and on the other side demand of blood increasing persistently. At the same time, Blood transfusion is a cornerstone of modern medical practice essential in almost every field of clinical practice either in emergency situations or as a necessary adjunct to modern and emerging Medicare. Role of Nanobiotechnology in this regard is commendable for helping healthcare sector by supplying substitute for the same. In the ages of Intellectual Property Rights, Laws regarding various issues of Blood deals with controversies and technical difficulties; even though getting various Patents regarding process and practices related to blood. As per The Patents Act, 1970 (39 of 1970); the section "Inventions - non-patentable" describes certain products and processes, which are not to be regarded as patentable inventions. The present communication deals with various related issues and discussions on the theme- whether blood comes under the purview of Intellectual property or not and various developments in IP regime of blood.

Keywords: Healthcare, Blood, Ipr Laws, India.

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Introduction

Blood is an essential component of the body which provides sustenance to life. There can be no greater service to the humanity than to offer one's blood to save the life of other fellow human-beings. At the same time blood, instead of saving life, cannot lead to death of the person to whom the blood is given if the blood is contaminated. As a result of developments in medical science it is possible to pre-serve and store blood after it has been collected so that it can be available in the case of need[1]. For the purpose of regulating its collection, storage and supply, blood was treated as a `drug' under the Drugs and Cosmetics Act, 1940 previously.

Ownership of biological material, more specifically Blood; have been much informed by the natural rights tradition. Insufficient attention has been paid to the strand in liberal political theory represented by Felix Cohen, Tony Honoré, and others, which treats property relations as socially constructed bundles of rights[2]. In accordance with that tradition, it is assumed that some combination of rights a person should have to blood or a particular item of biological material. It is to be discussed whether these qualify to be called “property” or “ownership” or anything related to “Intellectual property”.

Intellectual Property Rights are legal rights, which result from intellectual activity in

[1] *Common Cause v. Union of India and Others* on 4 January, 1996; Writ Petition (civil) 91 of 1992 (BENCH: S.C. Agrawal & G.B. Pattanaik; DATE OF JUDGMENT: 04/01/1996)

[2] B Björkman and S O Hansson. Bodily rights and property rights, J Med Ethics. 2006 Apr; 32(4): 209–214.

industrial, scientific, literary & artistic fields. These rights Safeguard creators and other producers of intellectual goods & services by granting them certain time limited rights to control their use. Protected IP rights like other property can be a matter of trade, which can be owned, sold or bought. These are intangible and nonexhausted consumption[3]. At its most basic level, intellectual property refers to ideas or information that spring from a person's mind[4]. Such know-how is necessary for research, for artistic and creative endeavors, for basic activities most of us engage in, and for operating business enterprises. The importance of such intangible property creates a conundrum, however. Proponents of broad legal protection for intellectual property generally argue that such protection is necessary to incentivize investment in creative and innovative activities that ultimately benefit society[5].

Over the last few decades legislative enactments and judicial decisions have adopted an expansive view of intellectual property. The subject matter eligible for protection has continued to expand significantly in recent years. This expansion has erased the clear delineation between patent, copyright, and trademark law. It has also led to overprotection of intellectual property in the form of overlaps that allow multiple bodies of intellectual property law to simultaneously protect the same subject matter. At the same time, some other concerns also evolved, whether physical bodies having intellectual characters (like blood) can be included under the regime of IP Law.

In the light of the above background, concern over the issue, whether blood can be included in the regime of Intellectual property or not, arises. As blood has not only physical properties to be reckoned as a individual's property; but it has also qualitative properties, which one carries and inherited through progenies. This very theme is discussed in this communication.

Health care scenario in India

In India, historically, health policy has centered on the idea of equity. In modern times, it has been extended to incorporate the subject of universal healthcare and the provision of affordable health care extended to all citizens of a country. Despite the focus on equity, accessibility, and quality, India shoulders a high morbidity and mortality burden[6] and requires innovative solutions to reduce them. After independence, India intervened directly in the health care sector by providing health services through a chain of public hospitals and primary health centers. But a variety of deficiencies plagued the efficacy of the health care system. One of the central drawbacks has been limited expenditure in the sector[7,8]. The National Health Policy, 2002, directed the State to commit to universal health care through a "realistic" consideration of capacity[9] (infrastructure and resources) as a key challenge toward making health care available to all. Expenditure on health has remained only approximately 1percent of the GDP in 2011–2012 [10]. Over the years, the State's inability to provide for the health needs of the population has resulted in the growth of the private health care sector. Currently, Indian health care is one of the most

[3] WHO, Quality Assurance of Pharmaceuticals, Vol 1, and Indian ed., Delhi: A.I.T.B.S. Publishers & Distributors, 2007; 86-96.

[4] Roger E. Schechter & John R. Thomas, Intellectual Property: The Law of Copyrights, Patents and Trademarks § 1.1 (2003).

[5] Geoffrey Karny, In Defense of Gene Patenting, Genetic Engineering & Biotechnology News, April 1, 2007, at 1, 1, available at http://www.genengnews.com/gen-articles/in-defense-of-gene-patenting/2052/

[6] Balarajan Y, Selvaraj S, Subramanian SV. Health care and equity in India. *Lancet*. 2011;377(9764):505–515.

[7] Duggal R. Healthcare in India: changing the financing strategy. *Soc Policy Adm*. 2007; 41(4): 386–394.

[8] Selvaraj S, Karan AK. Deepening health insecurity in India: evidence from national sample surveys since 1980s. *Econ Polit Wkly*. 2009; 44(40):55–60.

[9] MoHFW. *National Health Policy*. New Delhi: Ministry of Health and Family Welfare, Government of India; 2002.

[10] Planning Commission, Government of India. *Twelfth Five Year Plan (2012–2017): Social sectors* (Vol III). New Delhi: Sage India; 2012:4.

privatized systems in the world in terms of share of health spending in the private sector[11,12].

However, the 12th Five-Year Plan (2012–2017) had outlined universal health coverage as a central goal proposing an innovative strategy of combining insurance (Rashtriya Swasthya Bima Yojana), contracting out services, and promotion of generic drugs through prescription drug reforms[13]. Such innovative policies are critical for providing affordable health care and reducing the out-of-pocket expenses on the same. A significant fraction (72 percent) of such expenses on health care is incurred on the purchase of drugs and other medical devices[14]. Deregulation of drug prices in recent years had led to an increase in the prices of branded drugs within the country[15] and price control has been brought back partially. Consequently, access to affordable medicines remains a critical issue and any policy or other innovation that can reduce costs would be very useful.

Importance of Blood in Health care

For considerable time, human kind is facing the problem of blood shortage and on the other side demand of blood increasing persistently. According to one estimate blood is needed every three seconds, but less than 5 percent of the population donates blood[16]. Blood demand is approximately over 177 million pints (97 million liters) per year while only 100 million pints (55 million liters) of blood are available from donors per year globally [U.S. Hematologist World Health Organization (WHO), Geneva, Switzerland]. These figures evoke an alarming and frightening reality. In response to imminent blood shortages, industries and academicians have begun a quest to discover an ideal blood substitute. Within the human body, blood performs two primary functions i) Transportation of oxygen to various tissues and ii) Removal of carbon dioxide from the body. Hence, when developing a suitable blood substitute, we should consider both these factors viz. that it should imitate the oxygen-carrying capacity of the red blood cells as well as remove carbon dioxide from the body[17].

In recent years, blood shortage has propelled the search for an artificial alternative to blood transfusion, based on oxygen-carrying solutions[18]. Artificial blood substitute does not contain plasma, platelets or red and white blood cells, but contains oxygen carrying molecules e.g. hemoglobin or perfluorocarbons which function to transport and deliver oxygen to the body's tissues until the recipient's body restores missing red blood cells. Current blood substitutes are either Hemoglobin-based oxygen carriers (HBOCs) or perfluorocarbons-based oxygen carriers (PFCs). HBOCs utilize Hemoglobin, an actual component of red blood cells while PFCs utilizes perfluorocarbons for delivering oxygen to body tissues[19]. Substitutes of red cells are currently being developed for supplementation of blood e.g. to compensate for blood loss caused by trauma or during surgery[20].

[11] *Supra* note 7.

[12] Sengupta, Amit for Jan Swasthya Abhiyan. *Universalising Health Care for All*; 2012. Available form: http://www.phmovement.org/sites/www.phmovement.org/files/JSA%20Convention%20Universal%20Health%20Care%20for%20All%20-%20booklet.pdf. Accessed November 30, 2019.

[13] Planning Commission. *Twelfth Five Year Plan (2012â€“2017): Faster, More Inclusive and Sustainable*; 2013. Available from: http://econpapers.repec.org/RePEc:ess:wpaper:id:5302. Accessed January 20, 2020.

[14] Kumar AK, Chen LC, Choudhury M, et al. Financing health care for all: challenges and opportunities. *Lancet*. 2011;377(9766):668–679.

[15] Bhargava A, Kalantri SP. The crisis in access to essential medicines in India: key issues which call for action. *Indian Journal of Medical Ethics*. 2013; 10(2):86–95. Available from: http://www.ijme.in/~ijmein/index.php/ijme/article/view/30. Accessed January 10, 2020.

[16] Schimmeyer S. The search for blood substitute. Illumin- A review of engineering in everyday life Nov-2002; 5.

[17] *Ibid*.

[18] Winslow RM. Current status of oxygen carriers ('Blood substitute'). Vox sang 2006; 91: 102-110.

[19] *Supra* note 16.

[20] Philips WT, Klipper RW, Awasti VD, et al. Polyethylene glycol modified liposome-Encapsulated hemoglobin: A long circulating Red cell substitute. Pharmacol Exper Therapeut 1999; 288: 665-670.

There has been some concern over finding a suitable, cheap, abundant and safe source of Hb (hemoglobin), which can undergo chemical modifications to produce an effective blood substitute. To-date there are four potential sources of Hb viz., i) Expired blood; ii) Bovine blood; iii) Recombinant protein from microbes and iv) Recombinant protein from transgenic animals[21].

Nanobiotechnology and Hb formulations for substitution of Blood

Nanobiotechnology played a crucial role in the formulation aspects of Hb to fabricate it in suitable dosage form. Nanobiotechnology deals with the formation of nanodimentional structures of the biomolecules[22]. Patent Application No. WO9710268, assigned to Stichting central laboratorium, Amsterdam, is related to a process for manufacture of spray-dried Hb (hemoglobin) formulations which successfully shown that it remained stable during extended storage (over years) at ambient temperature and dissolves quickly (within 5 minutes) and easily on reconstitution and can be used for parenteral administration[23]. The US Patent No. 5217648 describes the process for preparation of Hb multiple emulsions (w/o/w) with high yield and high oxygen exchange capacity[24]. US patent No. 5352773 describes a stable Hb based composition and a method to store it[25]. US Patent No. 5281579 describes a method to produce purified virus-free Hb solutions[26]. S Patent No. 4439357 describes the process for obtaining hepatitis-safe, sterile hemoglobin solutions free of pyrogen and stroma, where red cell containing material is washed and then exposed to the beta-propiolactone[27]. US Patent No. 4526715 discussed the preparation of hepatitis-free Hb solution by a method employing washing and filtration[28]. In the 1930s, scientists collected free hemoglobin by lysing red blood cells and then transfused the unmodified Hb into animals. Short-term survival rates were good, but afterwards the animals experienced renal failure, intravascular coagulopathy, and vasoconstriction. In later studies it is revealed that most of the side effects are due to the presence of residual red cell stroma (Cell membranes) in the product[29]. US Patent No. 4473494 describes a method for the preparation of stroma free, non-heme protein free Hb[30].

Solutions of extracellular Hb have been demonstrated to have many therapeutic uses. US Patent No.s 5658879[31] and 5679638[32] describe the administration of stroma-free purified wild type hemoglobin to cancer patients in order to enhance the effects of chemotherapy or radiation therapy. US Patent No. 5614490 describes the use of stroma-free diaspirin crosslinked hemoglobin to increase the perfusion of tissues to treat stroke, ischemia and to treat hypovolemic, cardiogenic, and septic shocks[33]. US Patent No. 5428007 describes the use of recombinant mutant Hb with altered oxygen affinity to increase tissue oxygenation in order to treat burn victims[34]. US Patent No. 5631219 describe the use of recombinant mutant Hb with altered oxygen affinity to treat anemias, cytopenias, and cachexia, and to stimulate hematopoiesis[35].

Legal aspects of Blood transfusion

[21] Chandrashekhar Honrao, Uttam C. Banerjee and Parikshit Bansal; IPR and Technological Issues Regarding a Biopharmaceutical Formulation – Hemoglobin, Recent Patents on Biotechnology 2008, 2, 60-67.
[22] Perutz MF. Myoglobin and Hb: role of distal residues in reactions with haemligands. Trends Biochem Sci 1989; 14: 42-44.
[23] Tahey, H., Bakker, B., Bleeker.: WO9710268 (1997).
[24] Bessinger, R., Wasan, D.T., Sehgal, L.R., Rosen, A.L.: US5217648 (1993).
[25] Kandler, R.L., Spicuzza R, J.C.: US 5352773 (1994).
[26] Estep, T.N.: US5281579 (1994).
[27] Bonhard, K., Eichentopf, B., Kothe, N.: US4439357 (1984).
[28] Kothe, N., Echentopf, B.: US4526715 (1985).
[29] Cohn SM. Blood subs titutes in surgery. Surgery 2000; 42: 730-732.
[30] Tye, R.W.: US4473494 (1984).
[31] Nho, K.: US5658879 (1997).
[32] Teicher, B.A., Rausch, C.W., Hopkins, R.E.: US5679638 (1997).
[33] Przybelski, R.J.: US5614490 (1997).
[34] Fischer, J.J., Baserga, S.J.: US5428007 (1995).
[35] Rosenthal, G.J., Gerber, M.J.: US5631219 (1997).

Blood transfusion is a cornerstone of modern medical practice essential in almost every field of clinical practice either in emergency situations or as a necessary adjunct to modern and emerging Medicare[36]. The transfusion chain begins with donor considerations (whether their donation is safe for them to make and whether the donation is safe for any patient to receive). Once blood is collected, the safety of the blood product is a focus of activity (infectious disease testing, compatibility testing, necessary modifications such as irradiation or leukocyte reduction). The end-point of the transfusion process involves recipient considerations (proper identification of the unit and the patient, appropriateness of blood as the best treatment modality, administration of the unit and evaluation of the recipient)[37]. It is therefore, no longer acceptable to maintain a laissez-faire approach by accepting only the benefits of blood transfusion and ignoring its inherent risks[38].

In keeping with the advances in knowledge, technology and medical skills, medical law too has evolved and has seen the development as well as the refinement of important medico-legal concepts[39]. The revolution in blood transfusion practice has particularly created religious, moral, ethical and legal dilemmas[40,41]. These challenges coupled with the fact that, it is a form of transplant and associated with injurious complications to blood donors or recipients, calls for a critical assessment particularly that, some complications may be predictable and potentially prevented while others may go unnoticed only to present as blood transfusion injury. The risk associated with this essential service and the need for great caution in blood transfusion practice has been canvassed by many workers[42,43,44,45]. Medical practitioners who order blood or their patients are faced with the challenge of managing the blood transfusion needs of the patient in an evidence-based approach and balancing the expected clinical benefit with the medical and legal risks inherent in the transfusion of blood[46]. While the medical profession appreciates and respects the contributions of other health care givers and allied professions in some care services and treatments including blood transfusion, the "doctor-patient fiduciary relationship" is the foundation of a valid legal duty of care to any

[36] The Clinical Guidelines For The Use Of Blood Products In South Africa 4th Edition 2008 http://www.sanbs.org.za/PDFDocuments/services/Haemovigilance/Clinical_Guidenlines.pdf

[37] Transfusion Medicine. Available at http://www.aabb.org/tm/Pages/default.aspx accessed 16th September, 2019.

[38] Isbister JP, Shander A, Spahn DR, Erhard J, Farmer SL and Axel H. Adverse blood transfusion outcomes: establishing causation. Transf Med Rev 2011; 25:89-101.

[39] Caine N and Roux J. Informed consent and the mature minor. Pathcare pathology forum. Medical Ethics Edition 2010; 3:13-18.

[40] Beth Linea Carlson. Blood and Judgment Inconsistencies between Criminal and Civil Courts When Victims Refuse Blood Transfusions. Stetson Law Review [Vol. XXXIII available on http://www.stetson.edu/law/lawreview/media/blood-and-judgment-inconsistencies-between-criminal-and-civil-courts-when-victims-refuse-blood-transfusions.pdf cited 16th August 2019.

[41] Human Dignity and Bioethics: Essays commissioned by the President's Council on Bioethics. The President's Council on Bioethics Washington, D.C., March 2008 available at https://bioethicsarchive.georgetown.edu/pcbe/reports/human_dignity/ accessed September 9, 2019.

[42] Beal RW. The rational use of blood. Australia and New Zealand Journal of Surgery. 1976;46:309-313.

[43] Dhingra N. Making safe Blood available in Africa available at http://www.who.int/bloodsafety/makingsafebloodavailableinafrica.pdf cited 14th June 2014. Accessed January 8, 2019.

[44] Ejele AO. Blood sacrifice: How saving? 85th University of Port Harcourt Inaugural Lecture, 10th May 2012. University of Port Harcourt Press. ISSN 1119-9849.

[45] Orkuma JA, Egesie JO, Banwat EB, Ejele AO, Orkuma JH and Bako IA HIV Screening in blood donors: rapid diagnostic test versus enhanced ELISA. Niger J Med 2014; 23:192-200.

[46] The Clinical Guidelines For The Use Of Blood Products In South Africa 4th Edition 2008 http://www.sanbs.org.za/PDFDocuments/services/Haemovigilance/Clinical_Guidenlines.pdf

patient in the hospital setting[47,48]. It is also required of a hospital that, all the dealings in blood transfusion practice must always follow national and international guidelines[49].

A medical practitioner on oath at graduation pledges to consecrate his/her life to the service of humanity, practice the profession with conscience and dignity and to take the health of his patient as the first consideration irrespective of color, religion, gender, political affiliation and any other differences[50]. Besides these, s/he is regulated by the current general Code of Medical Ethics including those relating to the care of the sick which stipulates among others that; His primary responsibility of care is to his patient, his obligation at all times shall always be to preserve human life, shall owe his patient complete loyalty and all the resource of his science[51]. In 1980, the international society for blood transfusion (ISBT) formally endorsed the first code of ethics governing the practice of blood transfusion and this was later adopted and approved by the WHO, the league of Red Crescent societies and the General Assembly of ISBT on 5th September 2006[52].

Intellectual property protection in India with reference to blood

With the advent of Trade-Related Aspects of Intellectual Property Rights (TRIPS), the intellectual property (IP) regimes have changed in most World Trade Organization member countries. TRIPS agreement sought to harmonize IP protection across World Trade Organization member countries so that a minimum level of protection is available to all inventions in various sectors. India also came up with its own version of TRIPS-compatible IP regime which has been hailed by some as a "model" regime for developing countries[53]. The Indian pharmaceutical industry remained import dependent until 1972, deeming most of the drugs unaffordable[54]. Political and policy developments in the early 1970s such as the new patent acts of 1972 and Drug Price Control Order (DPCO), 1970, laid the foundation for a strong pharmaceutical industry in India. The Patent Act of 1972 did not allow product patents in pharmaceuticals and DPCO put a large number of drugs under price control[55]. The post-TRIPS regime has witnessed higher investment in R&D[56]. A detailed econometric exercise has shown a shift to a stronger IP regime that has resulted in greater thrust in the R&D activity in the sector and domestic firms

[47] Osime C.O. Understanding Medical Ethics in a Contemporary Society. Available on www.ajol.info/index.php/bjpm/article/download/47383/33763 cited August 16, 2019.

[48] Opinion 10.015 - The Patient-Physician Relationship available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion10015.page? Accessed October 14, 2019.

[49] Gorea R. K. Medico-legal Aspects of Blood Transfusion. J Punjab Acad Forensic Med Toxicol 2010;10: editorial 5-8 available at http://medind.nic.in/jbc/t10/i1/jbct10i1p5.pdf Accessed May 3, 2019.

[50] The Code of Medical Ethics in Nigeria. Medical and Dental Council of Nigeria Abuja FCT 2008. ISBN 978-33650-88.

[51] *Ibid*.

[52] A Code of ethics for blood donation and transfusion. International Society for Blood Transfusion. Available at http://www.isbtweb.org/fileadmin/user_upload/Code_of_Ethics/ISBT_Code_of_Ethics_update_-_feb_2011.pdf

[53] Rakesh Basant and Shuchi Srinivasan. Intellectual property protection in India and implications for health innovation: emerging perspectives, Innovation and Entrepreneurship in Health, 2016:3 57–68 available from https://www.dovepress.com/ accessed on 30-Jan-2020

[54] Mohammad A, Kamaiah B. The Indian pharmaceutical industry in post-TRIPS and post-product patent regime: a group-wise analysis of relative efficiency using nonparametric approach. IUP J Appl Econ. 2014; 13(1):47–61.

[55] Basant R. Intellectual property rights regimes: comparison of pharma prices in India and Pakistan. Econ Polit Wkly. 2007;42(39): 3969–3977.

[56] Jagadeesh H, Sasidharan S. Do stronger IPR regimes influence R&D efforts? Evidence from the Indian pharmaceutical industry. Glob Business Rev. 2014;15(2):189–204.

have also increased patenting in India and abroad[57].

A study of 165 health products in the pipeline in People's Republic of China, India, and Brazil showed interesting patterns[58]. Of these, 55 percent were Indian innovations with a sharp focus on chemistry-based innovations and on vaccines for communicable diseases. On the other hand, People's Republic of China focused somewhat more on biotechnological innovations and Brazil on plant-based ones[59]. Approximately 82 percent of the products surveyed were targeted toward therapeutic interventions, and 18 percent of the identified innovations were vaccines. Interestingly, approximately 10 percent (16) of the surveyed innovations had an exclusive focus on diseases concentrated in the developing world (mainly vaccines) while 90 percent of them focused on global diseases that affected both the developing and developed countries. The study also showed that almost all of Chinese and Brazilian and 83 percent of the Indian innovations were developed or discovered by domestic research institutions. Only 17 percent of the innovations in India relied upon technological in-licensing[60].

There are various Patents related to Blood by different countries including India are granted. These are tabulated in Table 1 enumerating Blood related Patents under categories of techniques, process, chemistry, instruments, devices and medicine[61].

Table 1: Blood related Patents under categories of techniques, process, chemistry, instruments, devices and medicine

Category	Patent no	Country	Title
Analytical	898/DEL/2006	India	A novel potentiometric biosensor to determine pottasium concentration in human blood stream
Techniques	EP2130045	Europe	A novel potentiometric cholesterol sensor for the quantitative estimation of total cholesterol in human blood serum
	IN170764	India	An improved blood analysis equipment
	JP5032560	Japan	Biosensor to determine potassium concentration in human blood serum
	US7790112	USA	Biosensor to determine potassium concentration in human blood serum

[57] Goldar B. Gupta I. Effects of new patents regime on consumers and producers of drugs/medicines in India. Report Submitted to the UNCTAD; 2013. Available from: http://wtocentre.iift.ac.in/UNCTAD/09.pdf. Accessed March 10, 2019.

[58] Rezaie R, McGahan AM, Daar AS, Singer PA. Innovative drugs and vaccines in China, India and Brazil. Nat Biotechnol. 2012;30(10): 923–926.

[59] *Ibid*.

[60] *Supra* note 53.

[61] Source: CSIR-URDIP, CSIR India Patent Database.html

	US8357275	USA	Potentiometric cholesterol sensor for the quantitative estimation of total cholesterol in human blood serum
Biological Science	IN101627	India	A process for the isolation of a blood sugar lowering principle from the seeds of eugenia jambolana
	IN102676	India	A process for the isolation of a blood a sugar lowering principle from the leaves of rivea cuneata
	IN178531	India	An improved process for the preparation of amebocyte lysate from blood obtained from carcinoscorpius rotundacauda (indian horse shoe crab)
			useful for the detection of pyrogen in vitro
	IN182444	India	An improved process for the preparation of purified tissue type plasminogen activator (tpa) - an enzyme useful as blood clot dissolving agent
	IN183289	India	A process for the preparation of a dipstick useful for the diagnosis of malaria based on detection of plasmodial lactate dehydrogenase in blood samples
Chemistry	IN140400	India	A process for the preparation of clottable fibrinogen from human or bovine blood plasma
Instrumentation, Applianc	IN134978	India	A strain gauge blood

es Devices			pressure transducer
Medicine	660/DEL/2015	India	Blood detoxifying lichen composition used in liver disorders
	IN127321	India	Separation of protein fractions from blood plasma
	IN176440	India	An improved process for the preparation of optically clear serum from blood
	IN182444	India	An improved process for the preparation of purified tissue type plasminogen activator (tpa) - an enzyme useful as blood clot dissolving agent
	IN232577	India	A blood transfusion system
	IN244123	India	A process for the preparation of a lipoxygenase inhibitor useful in human blood platelet aggregation from penicillium frequentans
	US6531166	USA	Use of betel leaf extract to induce ifn-gamma production from human peripheral blood t cells and as a th1 type immunomodulator
	US6703045	USA	Composition and method for maintaining blood glucose level
	US7045157	USA	Use of betel leaf extract to induce ifn-gamma production from human peripheral blood t cells and as a th1 type immunomodulator
	US7083587	USA	Blood transfusion system

Discussion

As per The Patents Act, 1970 (39 of 1970); the section "Inventions - non-patentable" describes certain products and processes, which are not to be regarded as patentable inventions. It said, Methods of diagnosis practiced on the human or animal body are excluded from patentability. Methods of diagnosis performed on tissues or fluids

including blood, which have been permanently removed from the body are, therefore, not excluded from patentability. Methods of therapy carried out on materials temporarily removed from the body, for example, when blood is circulated through an apparatus while remaining in living communication with the body, are not patentable (*cf* Calmic Engineering Co Ltd's Application, [1973] RPC 684)[62].

The role of commerce and economic transactions in health care in general, and the buying and selling of human blood in particular and other biological material, are among the most controversial issues in health policy[63]. With respect to property rights there are two major rival schools of thought in political philosophy namely "the natural rights theory" and "the social constructivist theory" of property[64]. According to natural rights theory, man is bound by a duty to God to preserve His creatures (including ourselves). We cannot carry out this duty efficiently without exclusive rights to land and other objects—that is, private property rights. On the other hand, according to the other view, society is free to choose the system of property rights that best promotes social goods, such as justice and economic productivity. One of the major tasks of government and judicial system is to issue laws that create and define such a system or rights covering all aspects of Human blood, its substitutes, its transfusion and other related issues covering all aspects of biological material. Property rights, taken in this sense, cannot exist independently of (some form of) tradition or government or of any kind of custom. It's underneath Intellectual issues should also be addressed before drafting any such legislation or enactment.

Several proponents of the social constructivist theory of ownership have provided systematic accounts of the components of the bundles of rights that constitute ownership. These include, th*e* right to possess, right to use, right to manage, right to income, right to the capital, right to security, incident of transmissibility, incident of absence of term, duty to prevent harm, liability to execution etc[65]. When it comes to biological material including blood, the major components of bundles of rights includes, Right to security in life. The right of a person to keep a part of her body, and not have it removed or destroyed; Right to security after death. The right of a person that a part of her body is buried or disposed of in the way that she wishes; Right to donate for removal in life; The right of a person to give up a part of her body without remuneration, to be removed in her lifetime; Right to donate for posthumous removal; The right of a person to give up a part of her body without remuneration, to be removed after her death; Right to sell for removal in life; The right of a person to give up a part of her body against remuneration, to be removed in her lifetime; Right to sell for posthumous removal; The right of a person to give up a part of her body against remuneration, to be removed after her death; Right to income. The right to receive the profits obtainable from the use of a biological material (such as the profits from a cell line) (This differs from a right to sell in referring to the profits obtained at points in time after the initial removal of the material.)[66].

The question of the ownership of the body is a very complex one, both in ethical and legal terms. Although there is now nearly worldwide recognition that no person can own another person, as this would constitute slavery and violate Article 4 of the Universal Declaration of Human Rights[67], this fundamental right is not always guaranteed in practice; the exploitation of child labor is but one grim example[68].

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[62] Controller General of Patents, Designs & Trade Marks, India. Manual of Patent Practice & Procedure (Third Edition – 2008) Office of the Controller General of Patents, Designs & Trade Marks, Mumbai. p. 79.

[63] *Supra* note 2.

[64] *Supra* note 2.

[65] Honoré T. Ownership. In: Gueast AG, ed. Oxford essays on jurisprudence. Oxford: Oxford University Press, 1961

[66] *Supra* note 2.

[67] United Nations. The Universal Declaration of Human Rights. New York: United Nations; 1948. [Accessed June 1, 2019]. Available from: http://www.un.org/en/documents/udhr/

[68] United Nations Childrens' Fund (UNICEF) Celebrating 20 Years of the Convention on the Rights of the Child. New York: UNICEF; 2009. [Accessed August 16, 2019]. The State of the World's Children. Special Edition. Available from:

The question of a person's ownership of his or her own body is more complicated[69] and has generated an ample output of literature, including from the philosopher John Locke, according to whom, "every man has a property in his own person"[70]. Other philosophers have proposed a different angle, which Stephen Munzer summed up in the phrase "persons do not own their own bodies but they do have limited property rights in them"[71]. One of the most important is the Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*[72], which is a cornerstone of bioethics and biorights[73]. Article 21 of the Convention, headed "Prohibition of financial gain," states: "The human body and its parts shall not, as such, give rise to financial gain." The Explanatory Report[74] to the Convention clarifies the meaning of "body parts," which includes "organs and tissues proper, including blood," but excludes "hair and nails, which are discarded tissues, and the sale of which is not an affront to human dignity." Blood is thus explicitly included in Articles 21 and 22. This is consistent with, among others, European Directive 2004/23/EC, which uses the term "donor" to designate "every human source, whether living or deceased, of human cells or tissues".[75]

Legal disputes regarding the commercial use of biological material including blood or its derivatives are widely discussed elsewhere. In Moore v. the University of California, California legislation said, on the disposal of human tissues; and the fact that the patented cells were different from those taken from Moore and could therefore no longer be considered as his property[76].

Conclusion

In conclusion, it can be assumed that the appropriate choice of a bundle of rights may differ for different types of biological material including blood, for instance according to how scarce they are and how important they are for the health of the person from whom they are taken. It is, for instance, probable that the disadvantages of a market system will be smaller, and the advantages greater, for material that can be duplicated, such as stem cells and genetic material (which certainly have intellectual properties) than for material such as complete organs, which cannot be duplicated. For the final analysis, ethical principles will have to be combined with empirical information about the actual consequences of different procurement and distribution procedures, both

http://www.unicef.org/rightsite/sowc/fullreport.php.

[69] Pattinson SD. Medical Law and Ethics. Third Edition. London: Sweet and Maxwell; 2009. Property in human organs and tissue; pp. 516–525.

[70] Locke J. The Second Treatise of Civil Government 1690. Austin, TX: Constitution Society; 1998. [Accessed June 1, 2019]. Of property. Available from: http://www.constitution.org/jl/2ndtreat.htm.

[71] Munzer S. A Theory of Property. New York: Cambridge University Press; 1990. p. 41.

[72] Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Council of Europe; Oviedo, Spain: Apr 4, 1997. [Accessed June 1, 2019]. Available from: http://conventions.coe.int/Treaty/en/Treaties/html/164.htm.

[73] Kits Nieuwenkamp J. The Convention on Human Rights and Biomedecine. In: Dahl Rendtorff J, Kemp P, editors. Basic Ethical Principles in European Bioethics and Biolaw. Vol. 2. Barcelona: Institut Borja de Bioèthica; 2000. pp. 325–332.

[74] Council of Europe. Explanatory report. Strasbourg: Council of Europe; 1997. [Accessed June 1, 2019]. Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Available from: http://conventions.coe.int/Treaty/EN/Reports/Html/164.htm.

[75] European Parliament, Council of the European Union. Directive 2004/23/EC of the European Parliament and of the Council of March 31, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Official Journal of the European Union. 2004; L102:48–58.

[76] *Moore v Regents of the University of California*, 793 P.2d 479 (Cal 1990).

for the individuals from whom the blood or biological material is taken and for those who depend for their health on the availability of such material.

With regard to patentability and relevant operational criteria in particularly complex cases such as in the case of cord blood, in which biological material is used to develop products that can potentially be exploited commercially, it is important that even when a patent is granted, detailed information on the limits to possible uses should be indicated. This is recommended, for example, by the Organisation for Economic Co-operation and Development (OECD), which provides that "license agreements should define the roles and responsibilities of the parties in the commercialization, if any, of the products and services arising from the use of the licensed genetic invention" (paragraph 1.8)[77]. Although the guidelines refer to genetic material, the general principle is certainly applicable to other types of biological samples including and with special reference to Blood. Therefore, the question in the objective of the study is forwarded for further detail intellectual discussion.

[77] Organisation for Economic Co-operation and Development (OECD) Guidelines for the Licensing of Genetic Inventions. 2006. [Accessed June 1, 2019]. Available at http://www.oecd.org/science/biotechnologypolicies/36198812.pdf.