Property and human genetic information

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Abstract

Do donors (of samples from which genetic information is derived) have some sort of pre-legal (moral) or legal property right to that information? In this paper, we address this question from both a moral philosophical and a legal point of view. We argue that philosophical theories about property do not seem to support a positive answer: We have not mixed our labour with our genes, and the human genome cannot be said to be a fitting object for private ownership based on some idea of self-ownership. An analysis of the term ‘property’ as seen from a legal perspective yields the conclusion that property is, at best, a linguistic prop whose real content has to be defined at least partially conventionally. Relevant interests that may be seen to be protected seem to be interests of privacy or interests against exploitation. To the extent that the logic behind the patent system holds true limiting incentives decreases innovation in society. A balancing of interest must take place, and we have to make sure that patent protection serves general societal interests and not just those of special interest groups be that inventors or donors.

Keywords Genetic information · Patent law · Property · Property rights · Donors

Our property is nothing but those goods, whose constant possession is establish'd by the laws of society; that is, by the laws of justice. Those, therefore, who make use of the words property, or right, or obligation, before they have explain'd the origin of justice, or even make use of them in that explication, are guilty of a very gross fallacy, and can never reason upon any solid foundation. A man's property is some object related to him. This relation is not natural, but moral, and founded on justice. Tis very preposterous, therefore, to imagine, that we can have any idea of property, without fully comprehending the nature of justice...

David Hume, (Hume 1978 [1739], p. 491)

Introduction

What is the property status of information derived from human genetic samples?¹ Most importantly, does the originator of the information—the donor—have some form of *private property right* (morally and/or legally, wholly or partially), to that information? Genetic information derived from humans (we use from now the abbreviation GI) is, of course, in many respects very different from other forms of property (land, resources, houses and so forth). It shares with the properties covered by ‘intellectual property rights’ the feature of being non-rivalrous: Use of the information in GI does not preclude other’s use, unlike land, material resources, houses, etc. Moreover, GI differs from objects that are easily understood as possible candidates for being property since it is derived from the human body—but once derived, GI exists entirely independently from any given body. If one chooses to donate a kidney, there is no reasonable doubt that the kidney is, in a sense, in one’s possession beforehand: We own our bodies in the sense that we have *self-ownership*, which is precisely why we can say that we donate—give away—a kidney. But do we give away information that somehow belongs to us when information is derived from a sample? We believe that this is yet

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an open question and that it therefore would be wrong to assume from the outset that GI should be subsumed under one or the other form of self-ownership. By self-ownership, we do not refer to one of the several sophisticated senses in which this term is used in philosophy (albeit our use may be compatible with one or more of those). Rather, we use the term self-ownership in the intuitive, colloquial sense: Most of us have the firm intuition that we owe, in some fundamental and inalienable way, our bodies, and that this ownership generates requirements of justice or morality: We have *rights* based on this bodily self-ownership, rights that entail that others cannot treat us/our bodies in certain ways.

While it is hard—or rather, morally extremely dubious—to deny that we own our bodies, the same cannot straightforwardly be said for information derived from our body, or so we will argue. We all seem to intuitively agree that your body belongs to you—it is your property, and it is even in certain senses inalienable. But let us consider the practice of ‘wastewater-based epidemiology’ where scientists analyse wastewater collected in the sewers of cities for instance to explore the drug-taking habits of those people who live in them?² We normally do not consider our bodily waste something that we ‘own’ (in any ordinary sense of the term), and thus, it seems even less meaningful to speak of individuals have any sort of ownership of information derived from this compiled material when it is grouped together, so to speak. Would our intuitions about the case change dramatically if the information was derived ‘more directly’, e.g. if blood samples were screened on a routine basis to see whether the proportion of different blood types remains stable? Maybe, but we would argue that this is not based on any infringement of self-ownership.

In the following, we focus on the GI derived from samples from humans (tissue, blood or other) and not the physical samples per se. While some may argue that this cut between the physical sample and the derived GI is artificial or misleading, we maintain that the most interesting theoretical issues arise when we focus on GI, not physical samples. GI may be obtained for a host of purposes and once obtained it may be used for even more. This raises some pressing questions about the ability to control the use of the GI. If some particular unit of GI leads to a medical breakthrough, to whom should the honour and the financial benefit accrue? To the original provider of the sample? To the technicians and scientists (or rather, their institution or firm) that derived the GI? The techs and researchers who made the analysis and found a new medical use? Some combination of those? In short, who owns, or has the property rights, over the GI, if property rights can be held

over GI in the first place, and what does owning GI mean? The ability to have courts denies access to use or to obtain a share of the benefit of the use by others?

Questions like these are relevant not just in (in-)famous instances like the cases of Henrietta Lacks (Skloot 2010) and the Havasupai tribe (Van Assche et al. 2013) but in almost all those situations where GI is used, e.g. to develop new methods to diagnose patients or to treat them in the various way. Because of recent technical breakthroughs relating to big data and personalised medicine made possible by the increased use of large collections in biobanks of samples and GI, such uses will increase dramatically in the years to come. For these reasons, the push to get access to and to use GI is going to increase. Also, this push will surely include the need to secure the commercial interests of the investors who will often need to go from ‘information’ to ‘application’ and eventually to ‘product’ or ‘procedure’. Therefore, the need for coordination of the—often conflicting—interests of a multitude of stakeholders such as patients, researchers, universities, and industry will rise. Determining the issues of property and ownership to GI may have huge repercussions, politically, scientifically, economically and morally.

Before proceeding further, a few comments on the issue of informed consent are in order. The principle of Free and Informed Consent (FIC) forms a bed rock of medical law. It originated in the aftermath of the atrocities of World War II and is now codified in a number of international fundamental rights conventions and charters including the European Convention on Human Rights (Article 8 on the right to private life) and by the Council of Europe international Biomedicine Convention (Oviedo Convention), e.g. Hellstadius and Schovsbo (2017). FIC covers a very heterogeneous group of different models ranging from very specific consents, over broad consents and dynamic ones to inferred consents, e.g. Cambon-Thomsen A (2004), Hansson (2009), Tutton (2010), Kaye et al. (2011) and for an overview Minssen and Schovsbo (2014). Determining the breadth and the scope of consents poses both practical and more fundamental issues. It has been argued that this procedure may be ethically flawed: Since all possible future uses of the GI (and with it the associated risks of privacy loss and exploitation) cannot possibly—given the nature of biobank research—be known at the time of collection, the donor’s consent cannot be adequately informed, and thus does not cover all future use in a valid manner (Lipworth et al. 2006). Nevertheless, many commentators agree that such uncertainty does not necessarily undermine the validity of the consent given (Eyal 2012; Sreenivasan 2003). One argument for this may be that, accepting that biobank research is in its nature characterised by such uncertainty (samples may be stored for several decades, during which new pressing topics for sample analysis may emerge), it is not ethically defensible to let the demand for fully informed consent override research benefits of a

² As it was done in a recent study which analyzed wastewater in over 50 European cities, see http://www.emcdda.europa.eu/news/2016/12/latest-data-reveal-drug-taking-habits-in-over-50-european-cities_en (accessed February 20 2018)

certain magnitude. Also the use of ‘dynamic consent’ which uses modern tools of communication to involve donors and offers choices *ex post* (Kaye et al. 2011) or the reliance of the acceptance of new uses by Ethical Committees or other surrogates, O’Doherty et al. (2011) may accommodate some of the criticism. These are questions still to be resolved; however, this is not our errand in this paper. We shall thus now leave the question of informed consent to future uses, as it in our view does not have a direct bearing on the discussion of the foundational nature of property in relation to genetic information.

In the following, we will seek to provide a moral and legal roadmap for navigating the murky waters of property and ownership *vis-a-vis* GI. We will first employ (philosophical) theories of property to establish starting points for understanding what arguments have been put forward in support of claims for ownership generally. Next, we will turn to law and analyse what role the notions play in a juridical context and see how law is constructing models for ownership with patent law as the example. Having thus established some positions in the philosophical and legal landscape for understanding the debate about GI, we turn to two pertinent themes: (1) How should we understand ‘property’ *vis-à-vis* GI and what does this imply for ‘personal ownership of GI’ and (2) what legal consequences does ownership to GI via patent law imply and what are the proper methods and limits of control in this context? Finally, we will summarise and discuss some general implications of our argument.

Theories of property rights

Before we embark on an analysis of the laws on ownership, we will first consider some of the common arguments for allowing/prescribing property rights in the first place, i.e. the philosophical theories of property rights.

Focusing for now on private property, *John Locke* provides the probably most widespread conception of, or line of argument for, private property. Locke’s seminal idea was the principle of original acquisition which implies that legitimate ownership of something rests on (a) acquisition of something that is either owned collectively (leaving ‘enough and as good’ for everyone else) or unowned and then (b) mixing one’s labour with it:

[E]very man has a property in his own person: this nobody has any right to but himself. The labour of his body, and the work of his hands, we may say, are properly his. Whatsoever he then removes out of the state that nature hath provided, and left it in, he hath mixed his labour with it, and jointed to it something that is his own, and thereby makes it his property. [...] That labour put a distinction between them

and common: that added something to them more than nature, [...] had done, and so they became his private right (Locke 2003, pp. 111–112)

Locke’s theory has generally been taken to concern the ownership of land and goods, and less explicitly with the self-ownership in the sense of ownership of one’s body. However, Locke also holds that self-ownership in this sense is a prerequisite for ownership of land and goods: It is exactly because “every man has a property in his own person” that the mixing of this property over his body with something un-owned results in his acquired ownership of it.

We have accepted the general line of thought, i.e. ownership of something is acquired by way of mixing one’s labour with it, in many respects (apart, reasonably enough, for the finer details of ‘leaving enough and as good for others’). If you (legitimately) own a piece of land, build a small workshop and mix your labour with wood from the trees of your legitimately owned piece of land and produce furniture, you *own* that furniture, which implies that you can use it or try to sell it for the price you want. Market transactions are simply extensions of this basic thought. But while we have accepted this conception in many respects, it is not as easily applicable to GI, e.g. in the case where one wants to claim that GI is *per se* private property of the original donor: We have not mixed our labour with our own genes or in any way *produced* them by merely existing, and hence, we cannot own it, at least not on Lockean grounds. Furthermore, Locke’s theory is not as easily applicable when it comes to mental labour (as compared with manual), and applying the theory to information brings about all sorts of complications mainly in qualifying the effort needed and in limiting the scope of the property right. These are illustrated well when Nozick famously asked: “If you pour a can of tomatoes into the ocean do you own the ocean or have you foolishly wasted a can of tomato juice?” (Nozick 1974, p. 175). On the other hand, Lockean theory indicates a path of argumentation that as we shall see below does in fact resonate with law. Thus, should someone analyse the composition of, e.g. a gene and identify its function in the body and indicate how it could be used for diagnostic purposes, Lockean theory would at least in principle open for a claim of ownership based on that mixing of mental labour with the genetic information. What remains is of course some markers for qualifying the efforts of the owner *in spe* and some mechanisms for delimiting the scope of ownership.

Another cluster of philosophical conceptions of property (exemplified, among others, by Kant and Nozick) focuses on *self-ownership*, the idea that all individuals have complete and full rights over their bodies, minds, and talents, and that infringing on these limits is morally reprehensible. Such a conception may be closer to the intuition that since we own our bodies, we also own the GI. However, geneticist will probably protest: Genes as such—understood as the human

genome—are not something that can be claimed by individuals. If anything, they are common property. Here, it may be counter-replied that our *specific* genetic make-up makes us who we are, and cannot be subsumed under the general heading of ‘the human genome’ (even if your specific house belongs to the general class ‘houses’, it is *your* house and not something held in common). But here it may still be said, drawing on the Lockean intuition, that you have not *done* anything to acquire your genome. It is ultimately a rather random mix of just four nucleotide bases that we all have in common.³

Still, this “my specific genome” line of thought probably is the closest we get to something which aligns with the intuition “I own my body hence I own the GI”. However, and assuming that the original sample was obtained in a legitimate manner, it is hard to see that bodily self-ownership automatically extends to GI: Surely, your heart belongs to you. But if a health scientist monitors your heartbeat—derives information from your heart—do you then by extension own that information? After all, the information does derive from something we believe trivially belongs to you, namely your heart. Furthermore, the concept of self-ownership and the idea that all individuals have complete and full rights over minds and talents arguably also extends to the ‘fruits of the mind’. Hence, this theory seamlessly allows for “I own the results of my creative efforts” arguments which may in effect compete with the “I own my body hence I own my GI” narrative.⁴

As can be seen, both the Lockean model and the theories of self-ownership do provide arguments both for and against private ownership of GI, but are clearly (and for obvious reasons) not formulated with GI in mind. Nevertheless, we find application of these theoretical considerations to GI in the field of law. The next step, then, is to explore how the general theories regarding property and ownership have informed the law(s) *vis-à-vis* GI.

Property rights to GI in law

In this section, we first describe how law uses notions such as ‘property rights’. Next, we zoom in on how GIs are in fact protected and in particular on patent law and GI.

³ We do not want to get embroiled further in the complex issue of ‘whole genomes’ and thus leave it open that special property rights to such may be justifiable, even if that raises further complications, e.g., in the case of monozygotic twins.

⁴ The former narrative is reflected in the Universal Declaration on Human Rights, Article 27(2) (“Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”) and International Covenant on Economic, Social and Cultural Rights of 16 December 1966, Article 15(1)(c) (“The States Parties to the present Covenant recognize the right of everyone: To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”).

Property rights

Taking as our starting point for the following Alf Ross famously proclaimed that the words “ownership” and “property” are “without meaning, without any semantic reference, and [one which] serve[s] a purpose only as a technique of presentation” (Ross 1957; 821 et. seq.) By this token, to ascertain whether something can be the object of property rights—and thus can be owned—and what legal effects ownership imply one must analyse the legal norms and ascertain what facts (F) are connected to which legal consequences (C). Ownership merely stands for the systematic connection that certain facts entail a totality of legal consequences (ibid.). By way of example (based on ibid): (1) If A has lawfully bought a car, (F) *ownership* is thereby created for her; (2) if A is the owner of a car, she has various legal remedies at her disposal including recovery (C). According to Ross the notion of ownership is not necessary to connect F to C; it does not add anything to the legal analyses to identify A as being the ‘owner’. This does not mean that concepts like ownership (and of ‘patent right’, ‘property’, ‘claims’, etc.) are not useful. They are but only because they allow us to present in a simple way the complicated legal construction based on a multitude of facts and conditions: By stating that “A owns the car”, we simply describe in a rather precise way something complicated, e.g. that A (being the owner) may recover the car if stolen, may transfer title, may claim damages if damaged etc. For the following discussion of patent law labelling something as ‘patented’ and someone as ‘patent holder’ does not in itself tell us anything about the legal consequences of having a ‘patent’ (being an ‘inventor’). In particular, one should not from the terms themselves seek to deduct legal consequences (a practice sometimes referred to in a derogatory way as ‘Begriffsjurisprudenz’). Note that this view about the meaning of *legal* terms and their relevant implications in the court is entirely consistent with the plausibility of all sorts of alternative forms of analyses *outside* the legal domain, including analyses that emphasise common use, ideal language analysis, etc. The point is ‘internal’, as it were, to the legal domain. But we hope to have shown (in the above) that in this specific context, conceptual analysis with roots in standard philosophical reflections about property rights do not give us robust reasons to claim that GI gives rise to donor’s property rights in the straightforward sense.

The notion of property right and the definitions of what can legitimately be owned etc. has changed over time and also varies from one culture to another (Nwabueze 2007; 248 et seq.). In the European countries, we know of the law distinguishes between the ownership issues regarding the physical embodiment in the form of the sample, and the GI. Generally, the former is dealt with under (general) property law (*right in rem*) and the latter—which is at issues here—by intellectual property law (IPR). IPR provide for exclusive rights to

information in the form of, e.g. literary and artistic works and databases etc. (copyright), signs used to indicate the commercial origin of goods or services (trade marks), the appearance of products (designs) and inventions (patent law). IPR's standard paradigm for regulating ownership includes norms which identify (a) something as an *object* of protection (for patent law 'the invention'), (b) someone as the *subject* of the rights pertaining to the object ('the inventor'/'patent holder') and (c) which provides for the specific *rights* to be exercised by the subject over the object ('exclusivity'). The same model is used for physical property even though those norms are often not found in a single piece of legislation but have to be deduced from various sources. The model is neutral (amoral) in these sense that the nature of the object does not matter: Legally speaking anything—including human beings and information as well as land and ice cream—may be owned by someone (else). To prevent perverse effects such as slavery, law provides for its own limitations notably through a system based on a hierarchy of norms. Thus, at the most basic legal level in the EU legal system the EU's Charter of Fundamental Rights proclaims in Article 1 that "Human dignity is inviolable. It must be respected and protected" and goes on to state in Article 2 that "Everyone has the right to life" and that slavery is prohibited (Article 5).⁵

Within these boundaries, law uses legislation, general principles and other norms to identify objects as property and persons (groups or the general) as subjects (owners) and to prescribe legal effects.

Legal rights to GI (and patents in particular)

To most lawyers, legal rights and obligations only exist between 'legal persons' (including corporations etc.) (Nwabueze 2007; 8 et seq.) For GI, the law provides for different kinds of rights to different kinds of persons (subjects) pertaining to GI. The rapid developments in technology tend to make it difficult for the traditional legal categories to clearly locate the rights in this or that law (e.g. Holman 2016), but the following laws have traditionally been the most important ones for GI in Europe: *Data protection law* give rights to identified or identifiable persons (called 'data subject') over 'personal data' including *their* GI. For this reason, a consent from the donor is needed both for collecting and using such GI.⁶ These rights

do not pertain to the information as such but protects the linking of the information to a specific person. In the EU, the protection of personal data has recently been upgunned. The GDPR now provides subjects with a variety of rights such as 'data rectification' (i.e. the ability to rectify inaccuracies) and a 'right to erase' ('right to be forgotten').⁷ The latter right applies when for instance the data are no longer necessary for the purpose for which they have been collected, the data subject withdraws his or her consent or objects to the processing of the information. The right to be forgotten does not apply, e.g. in cases where researchers can argue that data were stored for research and in the public interest. According to Neethu 2017, this may mean that researchers working in publicly funded biobanks may be able to retain data related to donors even if they request for withdrawal or erasure. Such continued use may be conditioned on 'pseudonymisation'.⁸ When the GI has been stored in a database, the owner of that database may claim *database rights* to protect his/her investments in the obtaining, verification or presentation of the data.⁹ For this reason, access to the GI in a database normally requires permission from the holder of the database right. Finally, when the GI has been analysed and a specific function of the GI has been identified (e.g. of the connection between a gene, a protein and a disease), that knowledge may be relied upon as the basis for an invention which may be *patented*. Should that happen, any commercial use of the invention requires the permission of the patent holder. The different kinds of rights are triggered by the specific conditions found in *their* legislation, provide for different legal effects and may point to different owners. Typically, the rights can be combined, and also, different subjects may claim protection at the same time if the conditions are fulfilled. For this reason, before GI is used (including collected), great effort should be taken to coordinate rights and obligations (normally by contracts).

In the following, we will focus on *patent law*. Patent law provide for exclusive rights to GIs as a means for increasing welfare. Without exclusivity—patent law assumes—rational companies would not invest in R&D for fear of free riders who would rather copy existing products or methods than face their own development costs. This overall narrative remains at best unproven (Machlup 1958). Recently, the patent system

⁵ The right to property is protected and this includes intellectual property such as copyright and patents. This right is not absolute, however, but may be regulated by law in so far as is necessary for the general interest (Article 17(1) and 17(2)).

⁶ More specifically, the processing (e.g. collection or use) of GI which is related to an identified or identifiable natural person is normally legal only if the "data subject" (for GI typically the donor) has given his/her consent 'for one or more specific purposes', see Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR).

⁷ GDPR Article 16 and 17. This 'right to be forgotten' was first developed by the Court of Justice of the European Union in its Judgment of the Court of 13 May 2014, Case C-131/12, Google Spain SL and Google Inc. v Agencia Española de Protección de Datos (AEPD) and Mario Costeja González, ECLI:EU:C:2014:317.

⁸ I.e. "the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure that the personal data are not attributed to an identified or identifiable natural person", GDPR Article 4(5).

⁹ Directive (EC) 96/9 of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases OJL 77, 27.3.1996, pp. 20–2, Article 7–9 (the so-called *sui generis* right).

(indeed the system of IPR) has even been described as a sort of secular faith resting on an unprovable beneficial effect on innovation (Lemley 2015). Even though this may not in itself render the patent system meaningless (Burk 2016), it clearly challenges the way the present system is devised and the basic criteria for establishing whether certain matters may be granted patents and what kinds of rights patent holders should be afforded. We do not intend to enter this debate. Instead, we discuss patent law for two reasons. Firstly, and as seen from a principal perspective patent, law is interesting because it presents a path to obtaining property rights to GI (based on the inventive effort) which runs *in parallel* to donors' claim (based on self-ownership). This aspect enables us to compare different arguments for property rights. Secondly, patent protection is hugely important since many medical breakthroughs depend on inventions derived from GI and it focuses on the potential economic value of GI and patent law is intended to capture that value.

It follows from the EU patent rules that the EU Member States are obliged to offer patent protection for any inventions, in all fields of technology including biotechnological inventions provided that these are new, involve an inventive step and are susceptible of industrial application.¹⁰ The right to apply for a patent belongs to the inventor, i.e. the physical person who conceived the inventive idea. The resulting patent right belongs to the applicant (often the inventor's employer) and entails the exclusive right to use the patented invention commercially, i.e. to prevent third parties from acting within the patent grant (unless the use is covered by a specific limitation (e.g. to experimental use)).¹¹ A patent right is normally described as a *negative exclusionary right* that enables the right holder to prevent third parties from working the patent. Thus, obtaining a patent does not imply a (positive) right to use the patented invention. For example, a patented pharmaceutical cannot be administered to patients before expensive and elaborate testing to obtain a market authorisation has been undertaken. In the same vein, patent law has traditionally been described as being *ethically neutral* and to not concern activities *pre* grant (such as the legality of the research leading to the invention) or *post* grant (the use of the invention).¹²

As it can be seen, patent law establishes a path to ownership to GI which runs in parallel to any claims based on the origin of the GI. The realm of patent law is defined by an important distinction between 'the human body' and 'element isolated from the human body or otherwise produced by means of a technical process'.¹³ Whereas the former cannot constitute an object for patent protection (an invention) the latter elements may. Patent protection under the EU rules is even possible if the structure of those artificially produced elements is (biochemically) identical to parts (genes or parts thereof, proteins etc.) which are found in the human body.¹⁴ The mere identification of the chemical structure of a gene is not enough to warrant protection. An intellectual (creative) effort in establishing an industrial application of the part (e.g. "this genes codes for that protein and may be used to treat such and such disease") and of disclosing this in the patent application is needed. Furthermore, patent protection is only available to inventions which are new and involve an inventive step (Minssen 2012, p. 23). Novelty is assessed on the basis of an objective and global standard and is not limited in time: Any use, anywhere and at any time may be held against the patent holder and lead to the invalidity of the patent. To satisfy the test of inventive step, the invention must not be 'obvious to a person skilled in the art'. The patentability requirements aims to secure that patent grants are only given as part of a quid pro quo where real innovative activities are rewarded with a limited period of exclusivity so as to enable the patent holder to recoup her investment costs through the internalisation of these costs in the price of the product. In doing so, patent law would ideally pursue the goal to grant a scope of protection that corresponds to the inventors' actual contribution to the state of the art.

Discussion

We divide the following discussion into two main issues: (1) What is the best way to understand property for GI, and what does this imply for 'personal ownership' of GI? and (2) what legal consequences does ownership to GI via the patent rules imply?

1. What is the best way to understand property for GI, and what does this imply for personal ownership of GI?)

Hume tells us, as we saw in the opening quote, that "[a] man's property is some object related to him. This relation is not

¹⁰ See European Patent Convention (EPC) Article 52, <http://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ma1.html>. Accessed 22 March 2017. This convention is binding to the 38 European countries (including the 28 EU countries) who are parties to the convention. At the international level, the basic patent law norms are found in The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which is an international legal agreement between all the member nations of the World Trade Organization (WTO), available at https://www.wto.org/english/docs_e/legal_e/27-trips.pdf

¹¹ See generally TRIPS Article 27(2) and (3) and in particular for patents on biotechnological inventions in the EU the Directive (EC) 98/44 of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (Biotech-Directive), in particular Article 8.

¹² E.g. Judgment C-377/98 of the Court of Justice of the EU of 9 October 2001, *Netherlands v Parliament and Council*, ECLI:EU:C:2001:523, para. 79.

¹³ For the EU, the ground rules for patents on biotechnological inventions are found in the Biotech-Directive Article 5.

¹⁴ This is unlike in the USA where the Supreme Court held in *Association for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013) that naturally occurring DNA (as opposed to cDNA) cannot be patented.

natural, but moral, and founded on justice.” Accordingly, rather than rely on some conception of self-ownership from which we may deduce what properly belongs to us, we may be much better off to consider what *moral* reasons there could be for deciding what form of property-status could and should be assigned to genes and GI. Such a model also aligns well with the legal understanding of ‘property rights’ as developed by Ross (as spelled out *supra*).

Colloquially, we normally think of property and ownership in terms of *private* property. However, at least three forms of property and ownership are relevant in the present context (for the following, see Waldron 2016): *common property*, where some system of rules provides that the property in question is available for the use of all of mankind (say, a public park, the open seas, or basic knowledge about the laws of nature); *collective property*, where some group of people, say, all electorates, decide the specific use of the property (Waldron uses “military bases and artillery pieces” as examples; the knowledge shared by a tribe or other (indigenous) community about beneficial properties of natural resources or of the producers of the Roquefort cheese about the making of that particular type of cheese would be other examples); and, of course, *private property*, where individual persons are entitled to rely on legal remedies to prevent others from using a certain resource such as land, a house or an invention or to obtain benefits from such use such as a musical composition being played on the radio.

The legal models for ownership vary. Or rather, the ways the state through legislation balances interests of the involved parties and the general public vary. For common property, the aim of the legislation is to keep access to *the public domain* open for the general public and thus free from appropriation by private parties or groups. For collective property, the legal regimes generally parcel out rights to members of the group. According to this model, all persons who fulfill the criteria for say producing Roquefort cheese have a right to join the group (and thus to designate their product as being (genuine) Roquefort).¹⁵ Private property rights may either allow the beneficiary (i.e. the owner) to prevent third parties from using the property by relying on injunctions issued by a court—i.e. a ‘property rule’—or to be compensated economically for use by third parties but without being able to prevent the use, i.e. a ‘liability rule’ (Calabresi and Douglas Melamed, 1972).

GI may fall in all three categories of property. GI as common property would simply be a piece of freely available information, like laws of nature or the decoded sequence lists of a gene. GI as collective property would, or would most plausibly, be something under the control of a group entrusted by the state (and ultimately the electorate), who decides use and non-use of the information. Other health data, e.g.

‘register data’ about large groups of the population, may be said to belong to this category: Access and use of the data is controlled by state agencies and researchers must apply and have permission from Ethical Review Boards. And GI as private property would be as other forms of property that falls under the heading ‘intellectual property’, like the exclusive right to use a patented gene to screen patients before administering certain drugs to them (personalised medicine).

In sum, GI *could* be subsumed under all of the standard conceptions of property—and different *kinds* of GI may fall into different forms of property ideas. This does not answer the question about what form of property we *should* assume for GI, nor does it answer anything concrete about who should own/control the GI. How, then, do we make headway on the question about private property and GI?

In the following, we focus on various normative reasons for and against individual property rights of the donor. Moreover, we set aside normative issues such as consent, manipulation, and deceit; in short, we assume that transfer of GI does not necessarily involve some form of moral wrong (as it did in the cases of Henrietta Lacks and the Havasupai tribe, see above).

Normative reasons for and against the donor’s private ownership of GI

What normative (i.e. moral) reasons can be mustered in defence of the following proposition: “The original donor has at least some form of private property right over GI derived from his or her body?” (Note that we are talking about some form of natural or pre-legal right: A donor and a scientist or a company may hence contractually agree to confer some form or other of private ownership to the GI in question, but that does not settle the question whether the donor has property rights *in advance* of such an agreement.) The focus here is ‘right’ in the moral, not the legal sense. A plausible conception of ‘moral rights’ is as follows: the central role they must fulfil is protection of some (vital) human interests. Rather than asking the question “what rights does X have” in some situation, the better approach is to ask first “what (vital) interests are at play here?” (This broad definition is compatible with, e.g. those who would argue that rights should be thought of protections of human dignity, insofar we have a (vital) interest in our dignity. It is not necessarily a strictly consequentialist conception of rights.)

So, what interests are at stake in the case of GI? As seen from the point of view of the donor, and setting aside issues about bodily harm (these are almost always negligible) and, as we said in the above, consent, manipulation, deceit etc.), it seems to us that there are two issues that come to the fore: issues of *privacy* and issues concerning *exploitation*.

However, before proceeding, we would like to note that these individual interests should be weighed against the interests of other parties: the interests of researchers, companies,

¹⁵ The name Roquefort is thus protected as a geographic indication for cheese in many countries.

and ultimately, our common, societal interest in advancing knowledge and medicine. Acknowledging that this is a simplistic picture, we group these together as the ‘interests of scientific progress’. In a nutshell, and setting aside the narrow capitalist interests of individual researchers and individual companies (that may or may not ultimately be legitimate if allowing those parties to pursue their narrow interests promotes our overall interest in advancing medical science), we have a common interest in finding new therapies, vaccines, cures, etc., because, or insofar as, they promote our welfare. With this *caveat*, let us focus on the interests of the individual donor.

Privacy

Individuals have a legitimate interest in privacy. While the exact boundaries of a sphere of privacy is the subject of an enormously complicated and rich debate, even when we just look at the field of bioethics (see, e.g., Mittelstadt and Floridi, 2016, part II), almost all of us are familiar with the thought that, in various ways, our privacy can be violated, and hence that we have *some* right to privacy—also in the context of GI (see, e.g. Tavani 2007).

Two questions, however, arise here. First, *is* our right to privacy compromised or violated by biomedical research into GI? And second, are individual property rights the only or best way to protect our interest in privacy?

Is our right to privacy compromised by research employing GI? While many may feel that, intuitively, having researchers “snooping around in our genome” compromises our privacy, this is not so straightforward. Exactly what is it that is breached? The issue at stake must be that researchers know something that the donor does not know, or something that the donor does not want others to know (about the donor). The latter case is probably of less practical importance, and in any event, it should not guide our thoughts about property of GI: We assume that all use of GI is consensual, so if some person does not want to participate in research by donating a sample, he or she should of course not be forced to do so, or should be given an option to participate on strictly anonymous terms.

The first case is more interesting: that researchers know something that the donor does not, and this constitutes a breach of privacy. Imagine, for instance, that geneticists discover that a donor is mistaken about his or her biological parents. Is *merely knowing* that a breach on the privacy of the individual donor? Note that we are not saying that *use* of that information cannot be wrong, e.g. if it is used to harass or blackmail the donor (or the donor’s parents etc.). These are trivially wrong actions. But is merely knowing such facts wrong, and does it constitute a breach of privacy? If it is, then, potentially at least, we would violate privacy every time we knew something about some other person which that person does not know, surely an implausible implication. In short,

merely knowing something—including knowledge about quite intimate affairs—does not in itself amount to a wrong (i.e. a violation of a moral right), and hence privacy is not violated *per se*. Another case may bring out other salient features. Geneticists can easily discover vulnerabilities to diseases—say, *byssinosis* (‘brown lung disease’)—of which the donor is unaware. Is that a breach of privacy? We aver that the uneasiness felt by some about some cases stems from, not the violation of privacy, but simply the (understandable) discomfort about being more susceptible to some disease or affliction. Bewildering complications arise when a health professional obtains medical knowledge of great importance for a patient: when, if ever (and how) should the health professional reveal knowledge (e.g. of risks) to a patient, especially in cases of incidental findings, or in cases where the patient “doesn’t want to know”. This is staple issue in medical ethics, e.g. Miller et al. (2008). The status of GI and private property may affect how we should view the duties of health professionals here; however, it is (we believe) unclear exactly how. If, for instance, GI really is private property, would this imply that health professionals have a more onerous duty to reveal (potentially unwanted) information? Or would it rather imply the opposite (*qua* respecting private property?) However, for our purposes, we need not disentangle such issues here.

As indicated above, this does not mean either that *obtaining* or *using* knowledge cannot be done in ways that are morally wrong. A doctor with knowledge of a patient’s genetic risk profile can wrongfully sell that information to employers or insurance companies behind the back of the patient. But merely knowing seems not to be a violation of any moral boundary. The question is whether the potential for wrongful use of knowledge threatens (vital) interests in a way generating an individual (partial or complete) property right to GI. This brings us to the second question: Are individual property rights the only or best way to protect our interest in privacy (*vis-à-vis* GI)?

There seems to something intuitively appealing in that line of thought: When a doctor or researcher sells information about a patient’s genetic risk profile to an employer or an insurance company, the wrongness of that action stems, partially at least, from a breach of that patient’s privacy: He or she would not have divulged the information if asked about it; it is, as it were, his or her private property. However, as the imaginary case shows, insisting on property rights will not necessarily protect the harmed party. This, of course, is not a knockdown argument against property rights, or rights in general: Rights will be violated, but may still be justified because they are valuable ways of protecting our interests. What may also be the case here is that conceiving of the patient’s right to privacy in terms of *property* rights is not necessarily the only, or the best, way forward. We feel moral outrage when we hear about a brutal physical assault, but few of us feel that the wrongness perpetrated concerns a violation of that persons

property rights to his or her own body. Surely, people have rights that protect them against gratuitous bodily harm, but need they be property rights? In the same vein, one may conceive of rights protecting against breaches of privacy that are not specifically property rights,

In sum, concerns about privacy do not unequivocally yield good arguments for individual property rights to GI. This brings us to the next question: exploitation.¹⁶

Another reason to think that individual persons have some form of property right over GI derived from their sample could be expressed as follows: Individuals are morally concerned about *exploitation*. If or when a company launches some product for (massive) profit, then, if not the original donor is somehow compensated, then he or she is exploited.

In the broadest sense, exploitation means, or at least involves, “taking unfair advantage of”. Someone—the exploited person—is denied something (a just reward, relevant opportunities, a fair share) by some other person,¹⁷ who in turn benefits (unfairly) from the exploitation (see, e.g. Wertheimer 1996). And surely, some forms of use of GI may seem exploitative: returning to the example where some geneticist has discovered that some person is mistaken about his or her parents, a rogue geneticist could exploit some vulnerable parent (biological or otherwise) in the form of blackmail, etc. This would be wrong, but wrong *qua* blackmail, not *qua* violation of property right. But this is not the sense of exploitation typically intended. Rather, it is the case where a person delivers some genetic information which is then turned into massive profit, without proper recompense to the donor. Of course, if a contractual agreement specified beforehand that the donor should receive some form of compensation in the event that his or her donation was instrumental in creating some lucrative drug or treatment, then it would be wrong to violate the terms of such a contract. But again, the wrongness resides not in a violation of property rights, but in the violation of a contractual agreement. In lieu of such a contract, it is hard to say that any property rights are violated if a company turns some GI into profit. Returning to the Lockean conception, the donor has not mixed his or her labour with the genes. In sum, considerations about exploitation, while a live issue, will not generate individual property rights over GI.

So, neither our interests of privacy nor concerns about exploitation yields the result that GI must be construed as necessarily involving some form of individual *property right* held by the individual, original donor. This, of course, is compatible with the conclusion that involving individual property rights may be an effective way of protecting certain interests, but that will be true only on a

case to case basis, not as a general conclusion. In this light, we can proceed to examining the question about property rights and GI from a legal point of view.

2. What legal consequences does ownership to GI via patent law imply and what are the limits of the patent holder's rights?

Including GI within the realm of patent law affects the ways inventors can or may use GI. On the general level, the market-based nature of patent law raises a number of issues. Rational companies following economic incentives through patenting for instance must be expected to focus on just profitable inventions (such as drugs) or methods (e.g. for curing diseases). Consequently, “diseases of the poor or the few” tend to be neglected by the patent system. However, as seen from a donor perspective the problems regarding the *exploitation* of patents based on GIs are normally not associated to the overall effects of the patent system. Instead, they relate to the distribution of the economic benefits that patent holders may derive from inventions which are derived from ‘the donor’s’ GI. Patent law does not acknowledge such concerns. In terms of the object of patent (property) rights, the patent system is based on a clear distinction between the naturally occurring parts of a human and the information derived from the body. Only the latter may be protected and only provided that the information derived from the human body has a certain quality, i.e. can be used industrially and satisfy the requirements in the patent legislation notably of inventive step. The distinction is neither legally clear nor ethically unproblematic (e.g. Hellstadius 2015), but it is the primary tool patent law uses to demarcate its domain. The object of patent law is not the naturally occurring gene but its isolated (artificial) counterpart, and patent protection is awarded only as a corollary to the creative effort of the inventor and with a view of furthering innovation in society. As far as the body in itself and its parts in their natural form are concerned, no patent rights may be acquired.

Whereas both Locke and the proponents of self-ownership would be able to relate to these distinctions, it is also clear that the focus just on the inventor may be *perceived* as being unjust. Moreover, the distinction between ‘nature’ (the sample) and ‘derivate’ (the information) is strained in practice (e.g. Hellstadius 2015, p. 367). After all, just like the inventive idea is *sine qua non* for the invention so is the sample. Patent law, however, is not distracted by this and offers little or comfort or means of control to donors. Patent protection is available to *anyone* who has invested mentally in the creation of the knowledge and has produced an invention in patent law’s sense. This is also reflected in the nature of the exclusive right which is granted to the patent holder. It is not a patent violation to have certain genes in one’s genome (such as genetic mutations that makes one vulnerable to a certain disease) or to pass

¹⁶ As should become clear below, we use the term ‘exploitation’ in a neutral, philosophical sense; we do not intend to be normative beforehand just by using that phrase.

¹⁷ We bypass here issues of ‘structural exploitation’ as they seem largely irrelevant to the case.

these on to one's children (even though the divisions of cells containing patented genes do in fact constitute 'copying' in patent law's sense. It is only if the patented genes are being used *commercially*, e.g. for making a kit for testing for the disease by using the gene that patent law kicks in and a violation occurs. In the same vein, there is no obligation arising under patent law for patent holders to share the economic benefit from inventions with the donors of the samples from which the GI has been derived. Patent law sees no competition of ownership interests since the rights and interests are perceived as arising out of totally different interests; patent law is a reward to the inventor and protects and recognises the intellectual effort. There is not even an obligation to work a patented invention so the patent may (and very often do) remain in a closed drawer and never actually used. Basically, patent holders may choose how to exercise their rights and may do so both in ways which some of us find to be sympathetic and other do not.¹⁸

Based on the reflections above, we think that linguistic analyses of the concepts of property or 'ownership' add little to the discussion about how the system ought to be. The patent system like other legal systems is a man-made construction and could—and should—be amended if it does not produce the wanted effects or has unwanted side effects. The exact boundaries for the property rights of X are not cast in stone. We would expect the boundaries to change over time and to reflect changes in technology, in culture and in values. This has happened throughout history. By way of example, Lessig reminds us that a certain point in time ownership of land included control of the airspace above the land so flying over someone's land constituted illegal trespassing (Lessig 2005). This did not mean much until the emergence of commercial air transport and then that particular legal consequence of ownership to land became intolerable to society and had to be abolished (which was done by the US Supreme Court in 1946¹⁹). For GI, we expect a similar development brought on by gradual changes in the underlying societal undercurrents. One could for instance discuss whether donors should have a greater say (or rather *a say*) in patent law. Presently, the EU rules on patent state that for inventions which are based on human biological material a prior informed consent must have been obtained. Disregarding this provision would not, however, seem to make the patent invalid (Hellstadius 369 et seq.). Maybe it should? Also, one could discuss whether genes, proteins, stem cells or other parts of the human body should continue to be patentable at all, whether the financial gains derived from such material should be distributed outside of the company which holds the patents or whether the patent system should be directed at serving broader goals such as the

common concern of mankind (Sommer 2013). We do not want to take a stance in these debates. We think however that the patent system should be devised in a way that includes the hopes, concerns and interests of *all* stakeholders. These interests naturally also include those of the patent holders. The basic aims of the patent system to increase overall welfare are very laudable. Moreover, donors who have volunteered to donate a sample would normally be interested in seeing the development or new drugs or medical procures on the basis of 'their' sample. If one allows a single donor to prevent the development of—say—a drug on the basis of 'her sample', who would be *exploiting* whom?

Summary and perspectives

To recapitulate, the key question in this paper is as follows: Does the originator (donor) of a sample have some form of private property right to the genetic information that can be derived from the sample? Mainstream philosophical theories about property do not seem to support a positive answer: We have not mixed our labour with our genes, and the human genome cannot be said to be a fitting object of private ownership based on some idea of self-ownership. Moreover, information derived from the human body is different from (parts of) the human body itself. An analysis of the term property seen from an internal legal perspective yields the conclusion that property is, at best, a linguistic prop whose real content has to be defined conventionally, or, at the least, from outside the legal domain. Law is a man-made thing, and we need to look at various normative reasons for *why* we should view GI as (potentially) involving private property rights. To do so, we need to identify what it is we want to achieve and how to best balance any competing interests against each other. Since the values and interests of the stakeholders and society at large constantly change, we must also accept that maintaining the right balances requires constant gardening. In this way, the exact legal effects of owning something changes over time. Turning again to the philosophical arsenal, property can be understood in either private, common or collective terms, and we see no decisive reason to fix property relations to GI in the private category. On a normative analysis, any pre-conventional *moral* right must be a necessary means to protect some (vital) human interest. Regarding GI, relevant interests that may be seen to be protected seems to be interests of privacy and interest against exploitation. However, merely knowing something about the genetic makeup of a person does not seem sufficient to constitute a breach of privacy (while *using* that knowledge may indeed be a violation of privacy). Protection against exploitation seems in this context seems to matter only when

¹⁸ Rules on 'compulsory licensing' found in some national patent Acts may prevent abusive uses but in practice those provisions are very rarely used.

¹⁹ *United States v. Causby*, 328 U.S. 256 (1946).

breaches of contract are involved; there seems to be no reason to say that protection against exploitation generates any pre-conventional rights of property. Furthermore, any interests against exploitation should be seen in the light of the benefits that may arise from exploitation. To the extent that the logic behind the patent system holds true, limiting incentives decreases innovation in society. Again, a balancing of interest must take place, and we have to make sure that patent protection serves general societal interests and not just those of special interest groups be that inventors or donors.

We think three main points emerge from this analysis

First, analysis of philosophical notions of property (private, common or collective), privacy or exploitation does not yield the conclusion that there exists some form of pre-conventional or natural right to GI held by the donor. Naturally, one may extract GI from persons in ways that infringe many rights (say, by use of force or manipulation), but these violations are not necessarily of private property rights. And there are ways of *using* GI (say, blackmailing) that are wrong, but again, these ways have little to do with private property rights. The intuition “I own my body, hence I own the GI” can, at best, be translated to “I own my body, and there are ways of deriving GI from my body that are wrong.” But given a competent donor freely consents, any issue concerning private property to the GI derived are matters of contractual agreement between the donor and the consentor. In other words, donors and researchers/possible patent holders may enter into a broad array of contracts, including contracts where the donor waives any rights to future benefit, without any pre-conventional or natural right has been violated.

Second, we should be careful about our terminology and in phrasing issues. In particular, one should not from terms such as property and ownership seek to infer legal rights or obligations. To establish the meaning of, e.g. ownership based on patent law, one should instead scrutinise the legislation and other legal sources to ascertain the particular legal consequences associated with patent protection. From this, it becomes clear, e.g. that patents cannot be obtained for the mere identification of the composition of genes and that private use cannot constitute an infringement. It also becomes clear that patent holders are under no legal obligations to share economic benefits with, e.g. the person from whom the GI, which has formed the basis of an invention, comes from and who may well claim to be the owner of that material. In the same vein, we should be careful not to focus too closely on the black letter law when evaluating the effects of legislation. Not even basic categories such as property rights are always clear and users may rely on

the legal control to, e.g. provide for open or even free access to use GI.

Third, having said that this, we also believe that it is important that law develops in ways that reflects underlying currents of philosophical and legal developments. The notions that an effort should be rewarded in law and that ‘(s)he who sows should also reap’ undoubtedly resonate deeply with moral and ethical sentiments that should also be reflected in the law as part of the overall balancing of interests. But again, these intuitions must also be balanced against less immediately personal interests, primarily the interests of scientific and, most importantly, medical progress. How exactly to strike that balance is a matter of policy rather than principle.

Finally, we want to sketch some practical implications of our line of thought: What are the consequences of our findings for the collection and use of GI? How can our analyses contribute to balance interests and take into account the hopes and concerns of the stakeholders?

We expect GI to become much more important in the future: ‘The world’s most valuable resource is no longer oil, but data’ the journal *Economist* recently proclaimed.²⁰ Due to the recent advances in health technologies such as personalised medicine and precision drugs, GI is no doubt going to be part of this. Hence, geneticists work with a hugely important and precious resource when they deal with GI. ‘Importance’ here should be measured not just in the company’s spreadsheet but also in terms of contribution to individual well-being. Such a development holds promises and poses threats both to individuals, to companies and to society. Hence, geneticists and other professionals working with GI have to become ever more sensitive to the plausible demands and interests at play. In a nutshell, they need to focus (even more) on the *responsible conduct* of their activities. We hope here to have helped in the following sense: Appeals to (pre-contractual) ‘private property rights’ should probably be ignored. Complicated balances need to be struck which accommodate for the often-opposing interests. Balancing societal interests in ‘openness’ and ‘sharing’ of GI against ‘privacy’ and ‘protection’ is inherently complicated. Our analyses suggest that to find those balances, one must adopt a pragmatic perspective and focus on issues and policies—and here, not the least potential contributions to the welfare of communities and individuals—rather than on property rights. Of course, the issue of property rights is but one concern, and perhaps not the most central one. Still, rights and property are powerful metaphors. Owning something—or not owning it—can make people feel powerful or helpless and may stifle debates and

²⁰ Issue of May 6th 2017, available at <https://www.economist.com/news/leaders/21721656-data-economy-demands-new-approach-antitrust-rules-worlds-most-valuable-resource>

discussions. As we have tried to demonstrate, it is normally not helpful to focus on issues such as ownership and (my) property in developing policies. Owning something is in reality a very fluent concept, and for GI, the borders between my genes, your genes' and our genes hardly makes sense. In a way law recognises this fluency. As we have seen GI may be owned—or 'owned'—by several persons at the same time. The insight from law is that what matters is not so much *who* owns *what*, but what interests are protected and what level of control someone may exercise over someone else.

On that note, our most general point can be expressed thusly: We should be wary when agents—be they individuals,²¹ groups (including NGO's) or communities (for instance ethnic communities²²)—claim 'intrinsic' or natural property rights of genetic information. By way of example, one of the authors of this paper has argued that even though patent law (as mentioned above in note 13) requires donors to give free and informed consent regarding patent applications based on 'their' GI, non-compliance with that obligation should not invalidate patents unless such non-compliance would amount to a violation of principles of *ordre public* or morality (Hellstadius and Schovsbo 2017). In the same vein, our analyses support the claim made by Neethu (2017) that sometimes researchers may be able to retain data relating to donors even if they 'want to be forgotten' (via pseudonymisation). As neither donors nor inventors nor any other agent have any pre-legal (moral) or *ex ante*-justified legal property rights to information derived from their genes or fruits of their minds, a balancing of interests needs to take place. Whether or not (and the extent to which) legal protections and limitations to the use, dissemination, patenting and, eventually, commercialisation of GI are mandated is a question that concerns protection of other interests rather than interests directly based on, or best expressed by, property rights. Central among these interests are privacy and exploitation. Other interests borne by these agents may be pertinent, but that is beyond the scope of this paper. In any event, these interests must be weighed against societal interest or what we have called 'interests of scientific progress', and this is a question of policy rather than principle. At this point, philosophers and legal scholars may contribute, but it is primarily a task for law-makers and other decision-making institutions.

Compliance with ethical standards

Ethical approval This article does not contain any studies with human participants performed by any of the authors.

²¹ See the landmark case *John Moore, Plaintiff and Appellant, v. The Regents of the University of California et al., Defendants and Respondents* (1990)

²² The *Havasupai* case springs to mind, even if this case is extremely complicated and many breaches of basic Responsible Conduct of Research was involved.

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