

The following comments relate to three papers that present evidence of the broad challenges that face us as ethicists when confronted with developments in areas of human understanding and conception. Though we are at times the ones to have inspired and advanced these developments, the human capacity for understanding and integration is not always as expansive as our capacity for creativity. Thus, we are often perplexed or challenged (and at times astonished at the challenge) by the ultimate ethical and other consequences of our creativity. And these challenges are not simplistic or basic in their implications; “our lives are likely to be more fundamentally transformed in the next few decades than in the past 1,000 years,” says author Jeremy Rivkin of genetic engineering and its commerce. The three papers that comprise this panel demonstrate the evolution from an idea’s fruition to the analysis of its impact and eventual resolution of the dilemmas it may pose. At conceptualization, the creator may not anticipate the implications – or the breadth of the implications – that may reside in application. By evaluating these analyses, perhaps we may be more sensitive to the consequences at the origin or inception of the idea, rather than once the consequences occur.

Since this is an emerging arena for ethical evaluation, perhaps the most effective perspective from which to begin is the free market, or European individualism. Where no regulation currently exists – or where we are evaluating the evolving regulatory environment in a developing arena – the free market approach offers a starting point from which to then build a scheme that serves the needs of relevant stakeholders. One can thereby evaluate the potential gains and losses to stakeholders as a result of increased or decreased regulatory constraints.

It should also be noted that in areas that present novel ethical challenges, that which is considered most provocative and vexing by one colleague may be accepted as rote by another who is far more confounded by an alternate query. Such is the case with the analyses presented by these three papers. For instance, though one examination focuses on whether certain biotechnological processes may be patentable (Meir), another presumes patentability via precedent and proceeds to evaluate the corporate environment in which the patents are held (Potts). Similarly, Meir is satisfied with the concept of a 20-year (actually 21-year as explained in his paper) limitation on patents, while Potts summarily explains that patent rights “can be extended for a considerable time.” Finally, in comparison to Meir’s support for current levels and extents of patent regulation, Potts instead suggests revisions in order to close “loopholes which allow companies to patent gene products from the same gene almost indefinitely.”

“Who owns my ideas about your body,” by Asher Meir

In exploring Meir’s analysis of the intellectual property regime for human stem cells, one cannot help but ask whether anything is wrong with our current regime, and whether anything can be gained in terms of more effective incentives or implications under a more or less constraining environment. Meir contends that current patent law application to issues involving stem cell research is sufficient “as long as the law is carefully applied and patents are given only to truly patentable inventions whose extent is clearly defined.” Since that is what the law itself requires, Meir seems to be supporting the current system and is simply advocating strong and consistent application of that system to this new area of patentable product.

However, Meir’s paper goes beyond this mere support for the legal regime and also addresses the key areas of possible contention. Though he still suggests that the law adequately responds to these ethical challenges, the contentions themselves form the internal debate of the discussion that ensues. Meir suggests a key balance for analyzing the challenges to patenting what is essentially something generated by the human body is “to effectively exploit the ability of this technology to alleviate human suffering and to advance understanding, while ensuring that scientific and commercial enthusiasm don’t (sic) trample human rights and human dignity.” This balance appropriately forms the essential and central point of Meir’s judgment in connection with stem cells as intellectual property.

In Meir's evaluation of the problems with patents (sec. 2.1), however, he evidences the appropriateness of the extant balance by suggesting the problems inherent in extremely faulty systems. For instance, he suggests the implications of an inadequate or, conversely, excessively expansive regime (*see, e.g.*, sec. 2.1.1 and 2.1.3). I would suggest that the arguments against the current environment remain more subtle and instead the sufficiency of the existing regulatory response could be more strongly supported by refuting these *subtle* challenges than by addressing only the most extreme. As an example, Meir mentions that "if the protection is too extensive, then too much may be invested in innovation." Undoubtedly, Meir's argument is irrefutable in its breadth. However, the more complicated and prickly question is exactly where the line is drawn between protection that is appropriate and that which is "too extensive." Meir also applies the same general analysis to the concern about inadequate protections and concludes that the current period of protection is acceptable. Without some discussion of the gray areas lingering between the two extremes, one is left in a bit of fairy tale limbo as Goldilocks' *only* remaining choice is the one in the middle, which is of course "just right." It is curious to me that somehow the patent duration of twenty years is coincidentally "just right" without further analysis, informed by free market considerations such as those Meir mentions in this section.

Later in his analysis, Meir leaves the question of the propriety of the current regime to evaluate its application with specific regard to the financial incentives involved in the system. The issue of compensating someone for the value of their tissues or the procedure required to access those tissues can be evaluated using a strictly economic or free market perspective. Yes, the individual may hold a unique and novel property right, however the same holds true for the seller of a particular piece of real estate. No two pieces of real property are exactly the same, yet the free market seems to work under those circumstances. This is not the situation of eminent domain as discussed in the paper but instead more appropriately compared to a basic house sale. If someone wants that unique piece of property and is willing to pay enough to encourage the owner to sell, a sale takes place. If not, then the sale does not ensue. Similarly, if someone wants biological materials and is willing to pay a sufficient price, the individual may be willing to sell. If not, then the sale does not ensue. The free market is sufficient under these circumstances since individuals may place different values and premiums on the use of their body parts for various purposes, among other personal distinctions. Relating this application to another of Meir's arguments, a free market approach will determine whether there are any implications to calling the payment "recompense for risk and discomfort" versus "payment for valuable tissue." There is no need for additional regulatory response in any of these areas since the market will respond with appropriate incentives and implications.

One comparison not raised by Meir but which seems intuitively applicable to the current analysis is the concept of slavery in America. Especially when addressing the evolution of a regulatory regime, the arena of greatest consternation is often the dystopic grey area where the law actually permits actions which promulgate unethical outcomes, such as the slave trade in U.S. past. In section IV, Meir discusses the intrinsic objections to property rights in stem cell research. The question of property rights in living organisms is addressed but no reference is made to one of the most startling issues of property ownership in U.S. history. Moreover, in discussing commodification, it would seem a natural extension to remind readers that it was the resulting degradation of the African-Americans that arguably led in part to the abhorrent treatment to which they were subjected as slaves. A national moral climate thereafter resolved that people could not hold a property interest in another person, thus perhaps resolving some of the ethical issues raised by Meir in one fell swoop.

I find myself convinced by Meir's conclusion that, notwithstanding challenges to the contrary, patent law does in fact satisfactorily respond to what many believe to be vexing questions. However, I cannot help but feel that the detractors of the current regime may have stronger arguments than those offered by Meir.

"Pharmaceutical Mergers and Genetic Technology: A Problematic Combination," by Michael Potts

Potts contends that perhaps the free market is allowing the over-concentration of firms involved in genetic research and technology and expresses concern over a number of ethical and legal implications. Again, however, Potts presumes we seek the middle position of “just right,” where perhaps market and stakeholder interests are best served by allowing extant incentives to prevail. For instance, though Potts is concerned about the current trend toward what he calls “mega-mergers,” there seem to be some compelling reasons to allow these mergers to take place. Potts’ own charts explain that mergers allow pharmaceutical firms to reap a number of benefits, many of which would provide value to varied stakeholders. Mergers allow the larger resulting firm to expand or deepen therapeutic areas, to achieve costs savings (which may be passed on to other stakeholders), to become a more attractive research partner (which may fuel research opportunities that might not otherwise exist), and so on.

Moreover, Potts’ own analysis highlights the increasing costs of research and development, and of marching a new drug through the FDA approval process. These costs and the pressures associated with them promote both innovation as well as expansion deeper into the biotechnology industry. By allowing mergers, if not outright encouraging them, the market is ensuring that research and innovation by the “megamergers” continue rather than allow the small biotech start-ups to be stymied by these increased costs and risks. Potts warns, “although smaller biotech firms exist and more are founded each year, and these mitigate market concentration, they usually do not survive as independent firms.” (p. 5). In the alternative, if we regulate to prohibit or restrict the mergers that form the basis of Potts analysis, we are likely to find a market replete with large pharmaceuticals having no experience in biotech, and small firms with an expertise in biotech but insufficient funding and other resources with which to take their innovations to the market. “It is starting to make more sense to buy small biotech companies outright and gain extensive access to their technology.” (p. 5).

Potts is persuasive in his admonitions against accepting the market processes as manageable or adequate. He stresses the impact on control over the exploitation of raw information if the mega-firms exert too much control over genetic resources. Potts contends that excessive concentration of control in this arena would lead to the extraction of exorbitant royalty fees in exchange for licenses to utilize the genetic product. However, if the fees become inappropriately high and firms designed to exploit these resources either cannot or choose not to engage in their use, then market forces will command a reduction in fees. Admittedly, one possible result is simply for these firms to pay the high fees and pass the costs to pharmaceutical consumers, resulting in a reduction in access to drugs for those who cannot afford the prices.

A balance must be struck, and in fact that is the foundation of Potts’ essentially rational argument. Perhaps the challenge to Potts then is the definition of his term, “over-concentration,” and a recommendation as to where to draw the line between that concept and “just right.” Though he sufficiently argues for his suggested practical steps to prevent over-concentration, I would suggest that he does not define the term such that the urgency that he evidently senses is transmitted to his readers. Finally, Potts concludes with a proposition that pharmaceuticals “show some self-restraint on mergers,” but he was more than persuasive earlier in his argument with regard to the value of the merger to both the large pharmaceutical and the small biotech merger partner, so it is not easy to see how this possibility might come to a realistic fruition.

“Stakeholder Care Theory: The Case of Genetic Engineering,” by Jamie Hendry

Hendry's analysis represents an extension of stakeholder theory in order to address an area previously considered by some scholars to be outside of the scope of this concept. Whilst I agree with both the value of Hendry's proposal to broaden the application of stakeholder theory, and with her ultimate conclusions, I find myself at odds with the process by which she arrives at these conclusions.

The first segment of Hendry's analysis discusses the application of two ethical theories to issues involving genetic engineering (GE) with regard to non-human subjects and the environment. The first theory she considers is utilitarianism. The author dismisses the applicability of utilitarianism to the ethical challenges posed by GE primarily because prediction about long-term outcomes associated with a particular action today is essentially impossible. However, later in her discussion Hendry quite specifically outlines a number of potential risks from GE. Since outcomes are almost always predictable only to a particular margin of error, utilitarianism is based in part on the decision maker's proclivity toward risk. Hendry is contending therefore, not that the outcomes are not at all known but instead that the risks involved of any specific outcome are not calculable. As such, utilitarianism can in fact be applied; it is simply that the risks might be so uncertain as to greatly outweigh the benefits. One might imagine, however, a situation where a life-saving pharmaceutical poses enormous risks, but those whose lives are at risk opt to submit to the drug nonetheless.

Hendry asserts that ISCT is also insufficient to respond to the ethical challenges of GE. My first dispute is with the implementation of the theory. Hendry contends that the hypernorms of a group are those determined by the application of a veil of ignorance. Rather, I would suggest this concept would be better validated in terms of the application of distributive justice than in ISCT. ISCT would, I submit, direct that hypernorms are determined by seeking the convergence of a number of sources that create a consensus around specific values and their application. In addition, notwithstanding either interpretation, I would dispute Hendry's conclusion that agreement is unlikely among decision makers with regard to non-humans, species or ecosystems. I do not suggest that such agreement is clear or easy, simply that it may be possible.

After dismissing the application of these two theories, Hendry then focuses her discussion on stakeholder theory. He suggests extension of the theory beyond Phillips' 2003 conclusion that stakeholder theory does not adequately provide for non-human or environmental subjects, raising the important consideration that humans may certainly speak on behalf of these subjects since many issues that surround them impact many if not all human stakeholders. Her discussion brought to mind the eventuality of a child as a stakeholder. The child may not be capable of consciously and deliberately accepting the benefits of a mutually beneficial cooperative scheme; yet one may not assert that a child is therefore incapable of being a stakeholder. Hendry explains furthermore that it is Phillips' contention that the environment cannot act reciprocally. This argument too seems somewhat foreclosed. If we act upon the environment, the environment responds.

In the end I conclude similarly to Hendry, although perhaps for different reasons. The single remaining issue left open by Hendry, and for which I have no suggestions either at this point, is how to determine or resolve conflicts among stakeholders or priorities when extending stakeholder theory. Is this a presumption in favor of humans over non-humans in light of conflicts, of non-humans over the environment? In considering the extremely pressing and conflicting issues raised by GE, I fear that a resolution of these challenges will be critical and, I expect, not prone to unanimity.