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In 2006, I published an article examining the rising use of racial categories in biomedical patents in the aftermath of the successful completion of the Human Genome Project and the production of the first draft of a complete human genome.[1] Ten years on, it now seems time to revisit the issue and consider it in light of the current era of "Precision Medicine" so prominently promoted by President Obama in his 2015 State of the Union address where he announced a $215 million proposal for the Precision Medicine Initiative as "a bold new research effort to revolutionize how we improve health and treat disease."[2]

In both cases, my animating concern has been to explore how the legal system of patent protection may be playing an inadvertent, or at least underappreciated, role in validating—and in some cases promoting—the construction of racial categories as biological or genetic constructs. The patent system is a particularly powerful, if obscure, site for such constructions because it accords legal force to the constructions of race as a genetic phenomenon that shapes practices from the lab, to the manufacturing facility, to the doctor's office, and to the market at large.

We see this most clearly in the original case study that led me to this area of inquiry: the story of BiDil, the first drug ever approved by the FDA with a race-specific indication—to treat heart failure in a "black" patient.[3] As I have shown, the underlying race-specific patent to BiDil drove how clinical trials were constructed, how data was framed and presented to the FDA and the public at large, and the way subsequent marketing programs attracted interest from doctors.[4] All this is based on scientific data that actually shows the drug would work in people regardless of race—indeed, the patent holder himself stated

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1. Jonathan D. Kahn, *Patenting Race*, 24 Nature Biotechnology 1349 (2006).

2. Press Release, The White House, Office of the Press Sec'y, Fact Sheet: President Obama's Precision Medicine Initiative (Jan. 30, 2015), https://obamawhitehouse.archives.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative [https://perma.cc/8MZ2-C8D3].

3. *See* Jonathan Kahn, *Exploiting Race in Drug Development: BiDil's Interim Model of Pharmacogenomics*, 38 Soc. Stud. Sci. 737, 737–40 (2008) (discussing the background of BiDil).

4. *Id.* at 740–44.

that he thought the drug would work in white people as well as black people.[5] Yet due to the legal and commercial advantages conferred by a race-specific patent, the corporate sponsors of BiDil racialized the drug, and by implication, biologized race—all with the active collaboration of the U.S. Patent and Trademark Office ("PTO") and the FDA.[6]

This dynamic is problematic for a number of reasons, not least of which is that it is scientifically ungrounded. As I noted in my original article, an editorial in *Nature Biotechnology* nicely disposed of this issue by stating that: "Race is simply a poor proxy for the environmental and genetic causes of disease or drug response. . . . Pooling people in race silos is akin to zoologists grouping raccoons, tigers and okapis on the basis that they are all stripey."[7] Beyond this, the reification of race as genetic has historically been a basis for oppression and stigmatization. Now more than ever, we must be on our guard against social, scientific, and legal practices that promote such misguided understandings.

In my original article on patenting race, I used the PTO patent search engine to query whether the "claims" section of any patents or patent applications referenced any of the basic racial and ethnic categories of the U.S. census (and cognate terms, such as "Caucasian" and "European" for "White," and "African" for "Black") or used the terms "Race," "Racial," "Ethnic," or "Ethnicity."[8] I then examined the patents to consider whether they used the terms in a manner that implied or asserted a genetic component to, or basis for, race.[9] Focusing on the claims section was particularly significant because the claims "specif[y] the legally operative scope of the patent, defining the formal legal

5. *Id.* at 743.

6. JONATHAN KAHN, RACE IN A BOTTLE: THE STORY OF BIDIL AND RACIALIZED MEDICINE IN A POST-GENOMIC AGE 21, 90 (Columbia Univ. Press 2013).

7. Editorial, *Illuminating BiDil*, 23 NATURE BIOTECHNOLOGY 903, 903 (2005) (internal citation omitted).

8. Kahn, *supra* note 1, at 1349–50.

9. As I noted in the original article, this is an admittedly subjective basis for sorting the patents. The categorization of patents that impliedly assert a significant genetic component to race or ethnicity is meant to exclude those patents that use racial/ethnic categories as one or more of a longer list of general demographic characteristics, usually employed for information organization, rather than for identifying or treating a particular physiological state. Thus, for example, patents on cosmetic products and database management were excluded. The categorization is meant to include those patents that use racial/ethnic categories as a basis for asserting a distinctive prevalence or etiology for a physiological condition, genetic variation, and/or drug response.

boundaries of the territory covered by an invention."[10] Below are the results of this first search from 2006[11]:

Table 1. Racial and Ethnic Categories Mentioned in U.S. Patent Filings, 1976–2006[12]

Category	Issued Patents: 1976–1997	Issued Patents: 1998–2005	Patent Applications filed from 2001–2005
Race	0	2	15
Ethnic	0	0	2
African-American/Black	0	4	11
Alaska Native	0	0	0
Asian	0	0	13
Caucasian/White	0	6	18
Hispanic/Latino	0	0	3
Native American	0	0	2
Pacific Islander	0	0	1
Total	0	12	65

Already in 2006, it was striking how the use of racial categories in patents and applications had burgeoned in the aftermath of the completion of the Human Genome Project.[13] The great initial irony here was that the post-genomic age was supposed to be a post-racial age. At a triumphant ceremony in 2000 announcing the completion of the first draft of the human genome, President Clinton declared: "I believe one of the great truths to emerge from this triumphant expedition inside the human genome is that in genetic terms, all human beings, regardless of race, are more than 99.9 percent the same."[14]

But as the 2006 tally of patents made clear, something else was going on. At least in the world of intellectual property, race seemed to be taking on a new and distinctive salience as a genetic marker capable of conferring legal and commercial advantage in the drive to develop

10. *Id.* at 1349.

11. *Id.* at 1350 tbl.1.

12. "Issued patents" have received formal approval from the USPTO. "Patent applications" were pending for review before the USPTO. USPTO policies enable public access to pending patent applications during the review period.

13. *See id.* at 1349–50 (noting a rise in using racial categories in gene-related patents as "clearly coincident" with the Human Genome Project).

14. Press Release, The White House, Office of the Press Sec'y, Remarks by the President, Prime Minister Tony Blair of England (via Satellite), Dr. Francis Collins, Dir. of the Nat'l Human Genome Research Inst., and Dr. Craig Venter, President and Chief Scientific Officer, Celera Genomics Corp., on the Completion of the First Survey of the Entire Human Genome Project (June 26, 2000), http://www.ornl.gov/sci/techresources/Human_Genome/project/clinton2.shtml [https://perma.cc/DSK2-RHYA].

new products for the biomedical marketplace. In the wake of BiDil's approval by the FDA, language of leaving race behind was superseded by language of using race as a stepping-stone to reach the promised land of personalized medicine.[15] And so patents geneticizing race continued to proliferate.

Coming back ten years later and conducting a similar search on the PTO's web site, the following results are present:

Table 2. Racial and Ethnic Categories Mentioned in U.S. Patent Filings, 2006–2016[16]

Category	Issued Patents: 2006–2016	Patent Applications filed 2006–2016
Race	3	38
Ethnic	13	89
African-American/Black	8	71
Alaska Native	0	0
Asian	8	54
Caucasian/White	23	108
Hispanic/Latino	1	17
Native American	6	7
Pacific Islander	0	0
Total	63	384

From 1998 to 2005 there were twelve uses of racial and ethnic categories in granted patents. Between 2006 and 2016 that number grew to 63. Similarly, with respect to the use of racial and ethnic categories in patent applications filed, the number of uses rose from 65 in the years between 2001 and 2005 to 384 in the years between 2006 and 2016. Far from abating with new genomic discoveries, the use of racial categories in biomedical patenting has increased aggressively.

What we see happening here is the normalization and routinization of inserting racial and ethnic categories into biomedical patents over the past decade. At a time when, rhetorically, many scientists and policy makers have been asserting the irrelevance of race in genetic research, we see a very different story unfolding in the world of intellectual property. Race, it is clear, is now understood as a standard and acceptable means to strengthen or supplement existing patent protections, regardless of its implications for reifying race as genetic.

One particularly recent and typical example can be found in U.S. Patent No. 9,241,991, titled "Agents, Compositions, & Methods for

15. Kahn, *supra* note 6, at 163.

16. The search for patents and patent applications was conducted on the USPTO website between July 10 and July 15, 2016.

Treating Pruritus & Related Skin Conditions."[17] As the abstract states: "This invention relates generally to a therapeutic use of TLR3 and TLR7 inhibitors to treat or reduce pruritus in a subject."[18] TLR3 and TLR7 are proteins that in humans are encoded by the TLR3 and TLR7 genes. Pruritus "is an unpleasant cutaneous sensation that evokes scratching behavior, which is distinct from pain that elicits withdrawal reflex of affected body."[19] The first (and most important) claim sets forth "[a] method of reducing pruritus in a subject, the method comprising administering to the subject a therapeutically effective amount of a toll-like receptor (TLR) 3 or TLR7 inhibitor, thereby reducing pruritus in the subject."[20] So far, so good. But then moving down near the end of the list we come across Claims 17–19 which state: "17. The method of claim 1, wherein the subject is a black African[;] 18. The method of claim 1, wherein the subject is a mammal[; and] 19. The method of claim 1, wherein the subject is a human."[21]

There are several things to note here. First, there is the qualification of "black" African. On the one hand, this clearly is intended to try to offer greater specificity than the geographic continental term "African." The implication being that "black" Africans can and should be distinguished from non-black Africans, whether those of more recent European or Indian settler populations in Southern Africa who do not code as "black," or those people from Northern Africa who might identify as Arab, Bedouin, or Berber, etc., who also do not generally code as "black." This specification is similar to that of "sub-Saharan African" also used in some patents as a qualifying term. But whereas "sub-Saharan African," while still problematic (see below), at least consistently uses geographic specifications for its population designator, "black African" mixes two taxonomies: geographic and racial. The patent never defines what is meant by the term "black." Is it purely a phenotypic description referring to skin color? If so, one could hardly say that dark skinned Africans have a uniform level of melanin in their skin that renders them all uniformly definable as "black." Indeed, how much melanin does it take to make an African into a "black" African? Of course, one might argue that the patent is merely employing terms that invoke common sense social understandings of who constitutes a "black African," but where else in complex biomedical patents do we ever see applicants similarly relying on such ill-defined "common sense" understanding of technical terms that are central to delineating the scope of the patent?

17. U.S. Patent No. 9,241,991 (filed Oct. 21, 2011).

18. *Id.* at [57].

19. *Id.* at col. 1 l. 30–32.

20. *Id.* at col. 69.

21. *Id.* at col. 70 l. 54–59.

Beyond the ambiguity of the term "black African," there is the even more problematic implication that this poorly defined term somehow has genetic salience. The patent, after all, is about administering a substance that affects gene function.[22] Singling out "black Africans" for a distinct claim is necessarily premised on the idea that "black African" genes are somehow different from the genes of other racial groups.

This leads us to the second deeper problem, the geneticization of race through patent law. Claim 17 specifies that the subject is a "black African," and Claim 19 specifies that the subject is a "human."[23] Of course, black Africans are a subset of the larger group "human." It would seem odd to allow a patent to cover a subset of a larger group, and indeed, the doctrine of "double patenting" would seem to prohibit such uses. Among other things, this doctrine prevents essentially claiming the same subject matter twice in different ways.[24] The contrast between Claim 18, where the subject is a "mammal" and Claim 17 where the subject is a "black African" is instructive here. Making separate claims for using the invention in a "human" and a "mammal" would not be double patenting, even though the category "mammal" entirely contains the category "human," because the category "mammal" also contains animals that are physiologically and genetically distinct from humans. Therefore, it would not be obvious that a therapeutic agent would work in other mammals as well as in humans. In contrast, one cannot claim with any scientific rigor that "black Africans" are physiologically or genetically distinct from other "humans" such that it would not be obvious that the therapeutic agent would not work in all humans if it worked in black Africans. That is, given the essential genetic unity of the human race and that "[p]ooling people in race silos is akin to zoologists grouping raccoons, tigers and okapis on the basis that they are all stripey,"[25] singling out "black Africans" for a claim distinct from "human" simply makes no sense. And yet, the patent office saw no apparent problem here. The underlying logic of accepting the separate black African claim can only be that the patent office consider that as human is to mammal so too is black African to human—or human:mammal ~ black African:human. The implication here is that, in the face of all scientific evidence to the contrary, the PTO has sanctioned the idea that in the larger category of "human" there are subjects who are physiologically and genetically distinct from "black Africans." So much for the genetic unity of human kind.

22. *See supra* text accompanying notes 17–20.

23. *Id.*

24. *See* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 804 (2015) (defining double patenting).

25. *Illuminating BiDil*, *supra* note 7, at 903.

Ironically, this makes sense considering that to reach this decision, the PTO first had to accept the (mistaken) "common sense" idea that "black African" is an obvious category in no further need of definition. From there, it is a short step to unquestioningly accepting the further (mistaken) "common sense" idea that there is a genetic basis to race. In short, when it comes to race, the PTO (like many patent applicants) effectively throws out scientific rigor in favor of common sense social understandings of race.

To some extent the PTO itself has been complicit in promoting this dynamic. As I have noted in earlier work, in December 2008, at a quarterly meeting of the PTO's Biotechnology, Chemical and Pharmaceuticals (BCP) technology groups' "customer partnership," PTO quality assurance specialist, Kathleen Bragdon, gave a presentation on "Personalized Medicine" in which she suggested that the PTO would likely *require* the inclusion of race specific data in certain patent filings using genetic correlation studies because the PTO considered ethnicity to be an "unpredictable factor" in such studies.[26] Presumably the idea here was that certain genetic variations, or alleles, have been observed to occur at different frequencies in different ethnic groups. What Bragdon failed to consider was that ethnicity itself was not an unpredictable factor but rather was an "unpredictable art"—that is, the means by which ethnicity itself is constructed and applied are often vague and variable —and certainly rarely defined in biomedical patent applications.

Typically, patent applications employ such overbroad, outdated nineteenth century categories as "African," "Caucasian," and "Asian" without offering any substantive definition of what they mean by those terms. Sometimes, they may go so far as to state that a term such as "African" means someone having "origins" or "ancestry" from Africa or perhaps even "sub-saharan Africa"—but of course does not consider the fact that if we go back far enough we *all* have origins in sub-saharan Africa, or that if we only go back a few hundred years there are substantial "African" populations with recent ties to parts of Europe and Asia—populations are not static, and so neither are genes.[27] Yet, instead of requiring patent applicants to better define the racial or ethnic categories they employ, Bragdon intimated that they should use these same imprecise categories *more*—indeed as a matter of *routine*. While the PTO later walked back these comments somewhat, replacing the word "ethnicity" with "patient populations"[28]—the message and general orientation of the PTO remains clear, and is born out in the

26. Kahn, *supra* note 6, at 141–48.

27. *See, e.g.*, Jonathan Kahn, *'When Are You From?' Time, Space, and Capital in the Molecular Reinscription of Race*, 66 Brit. J. of Soc. 68, 70 (2015) (discussing how all ancestry is shared).

28. Kahn, *supra* note 6, at 142–43.

evident continued rise in the use of racial and ethnic categories not only in applications, but in granted patents as well.

It is now clear that patenting race has become a routine, normalized, and even incentivized practice in biomedicine. Whether individual scientists particularly wish to include race in any given patent application, it is clear that their technology transfer offices and patent attorneys do. We may be touting the coming age of precision medicine, but there is nothing "precise" about how these patent applicants use racial categories in their filings—or for that matter in much of the underlying research.[29]

It does not have to be this way. There are some rare examples where PTO patent examiners have questioned how race was being used in particular patents, and there is an excellent example from the European Patent Office (EPO) of some more thoughtful and productive ways to think about race in the patenting process.

First, the PTO examples. There are several examples where initial patent applications included racial categories but the final granted applications had no such references. For the most part, when reviewing relevant patent prosecution documents exchanged between applicant and patent examiner, it is unclear why the race-specific claims were ultimately dropped. Often, it appears that the race-specific claims were merely casualties of the common process of give-and-take between any patent applicant and examiner where the examiner is arguing that the patent actually states claims for more than one specific invention and so requires the applicant to make an "election" among claims to make sure that the final patent is coherent and limited to one particular invention.[30] In this process, the race-specific claims, which are often ancillary to the central claims of the patent, tend to go by the wayside.[31]

29. *See, e.g.*, CATHERINE BLISS, RACE DECODED: THE GENOMIC FIGHT FOR SOCIAL JUSTICE (2012) (examining a shift to race-conscious research in various sciences); ANN MORNING, THE NATURE OF RACE: HOW SCIENTISTS THINK AND TEACH ABOUT HUMAN DIFFERENCE (2011) (exploring different conceptions of race).

30. *See, e.g.*, Kenneth Horton, *How to Deal with Restriction Requirements in Patent Applications*, INSIDE COUNSEL (Feb. 5, 2015), http://www.insidecounsel.com/2015/02/05/how-to-deal-with-restriction-requirements-in-paten [https://perma.cc/WH99-H67D] (discussing the election of species requirement).

31. Examples include U.S. Patent Application No. 12/785,060, ultimately granted as U.S. Patent No. 8,535,887. The application specified a claim "[a] method for estimating a probability that a patient having a chronic HCV genotype I infection will achieve a sustained viral response to combination therapy with a pegylated IFN-α-2 and ribavirin . . . wherein the patient is self-identified as African American or Caucasian . . . ." U.S Patent Application No. 12/785,060 claim 19. The final patent contained no such racial references. '887 Patent. Similar changes are evident in Single Nucleotide Polymorphisms Associated with Renal Disease, U.S. Patent

In one case, however, patent examiner Juliet Switzer rejected two claims using the terms "African-American" and "Caucasian" for being "indefinite."[32] Here the underlying operative Claim 35 covered "[a] method for identifying susceptibility to cardiovascular disease in a subject, comprising: obtaining a sample from a human subject; and determining if the sample contains a risk allele of ACE-associated SNPs rs4290, rs7214530, rs7213516 or combinations thereof."[33] The subsequent race-specific claims asserted, "[t]he method of claim 35 wherein the subject is an African-American human male or female," and "[t]he method of claim 35, wherein the subject is a Caucasian human male or female."[34] In response, the applicant struck the race-specific claims and the final patent as issued contained no claims referencing race.[35]

Switzer's rejection of racial categories as "indefinite" occurred in 2012—four years after Bragdon's presentation urging the use of racial categories in biomedical patents. So clearly, since that time some space has opened up in the patent review process for more nuanced and critical conceptions of how to deploy race in patenting. Yet, as an institution, the policy of the PTO toward the use of racial categories in biomedical patents has not been formalized. It lacks coherence and seems to vary on a case-by-case basis depending on the particular examiner involved.

Thus, for example, in his review of Patent Application No. 12/867,680, "Susceptibility Variants for Lung Cancer," examiner Joseph Dauner initially challenged a claim asserting a method of identifying a susceptibility gene "wherein the individual is of an ancestry that includes Caucasian ancestry,"[36] stating that "[t]his ethnic group is considered indefinite because it is not clearly defined in the specification and there is no art recognized definition for the group."[37] Here, however, the applicant, the Icelandic firm Decode Genetics, pushed back. It

Application No. 12/864,218, granted as U.S. Patent No. 9,102,983; Vaccine Peptide Combinations Against Cat Allergy, U.S. Patent Application No. 12/602,313, granted as U.S. Patent No. 8,551,492; and Methods & Drug Products for Treating Alzheimer's Disease, U.S. Patent Application No. 13/346,081 granted as U.S. Patent No. 9,102,666.

32. JULIET SWITZER, U.S. PATENT & TRADEMARK OFFICE, OFFICE ACTION SUMMARY: U.S. PATENT APPLICATION NO. 12/598,265, at 4 (Mar. 23, 2012).

33. U.S. Patent Application No. 12/598,265 claim 35 (filed Apr. 30, 2008).

34. *Id.* at cl. 36–37.

35. Polymorphisms in Genes Affecting ACE-Related Disorders & Uses Thereof, U.S. Patent No. 9,012,143 (issued Apr. 21, 2015).

36. U.S. Patent Application No. 12/867,680 claim 16.

37. JOSEPH G. DAUNER, U.S. PATENT & TRADEMARK OFFICE, OFFICE ACTION SUMMARY: U.S. PATENT APPLICATION NO. 12/867,680, at 16 (Jan. 19, 2012).

amended the claim by adding that "Caucasian ancestry is determined by self-reporting," and asserting that this was "a standard approach used by scientists in the field and recommended by the FDA (see Exhibit 1, e.g. at p. 4)."[38] The FDA document referenced here was a 2005 "Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials."[39] The section on pages 4–5 referenced by Decode Genetics states: "We [the FDA] recommend that study participants self-report race and ethnicity information whenever feasible, and that individuals be permitted to designate a multiracial identity."[40] Satisfied by this response, Examiner Dauner withdrew his indefiniteness objection and the race-specific claim was allowed to stand.[41]

Here is a classic example of "mission creep," whereby an FDA regulatory guidance intended to promote the collection of racial and ethnic data in drug trials was referenced to support a very different and much more explicitly geneticized use of racial categories before a different regulatory agency, (the PTO), for a very different purpose, (patent protection). Significantly, Decode Genetics, in referencing the FDA Guidance, did not draw attention to its very important caveat that these racial categories comported with those promulgated by the Office of Management and Budget for use in such data collection endeavors as the Census, and that "[t]he OMB stated that its race and ethnicity categories were not anthropologic or scientifically based designations, but instead were categories that described the sociocultural construct of our society."[42] The FDA allowed for self-reporting of race while recognizing that such usages were social, not genetic, in character. In its patent application, however, Decode was clearly and directly using the category "Caucasian" as specifically and explicitly of genetic significance. Decode used the reference to the FDA, a coordinate federal agency, as authority for its claim. This apparently was sufficient for Dauner who withdrew his objection. Yet nowhere was the point made that self-identification as "Caucasian" has no proven relevance to establishing anything about the genetic profile of any given individual.

38. Reply to Office Action of Jan. 19, 2012 at 18, U.S. Patent Application No. 12/867,680 (July 12, 2012).

39. U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: COLLECTION OF RACE AND ETHNICITY DATA IN CLINICAL TRIALS (2005), https://www.fda.gov/ohrms/dockets/98fr/2002d-0018-gdl0002.pdf [https://perma.cc/6Y4S-E3GT].

40. *Id.* at 4–5.

41. DAUNER, *supra* note 37, at 2. Ultimately, the race-specific claim was deleted based on an independent technical objection that it stated an "improper Markush grouping of alternatives," meaning that the claims "do not share a substantial feature and/or common function/use that flows from the substantial structural feature" of the patent. *Id.* at 16.

42. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 39, at 3.

Again, such an approach is about as scientifically rigorous as grouping raccoons, tigers, and okapis on the basis that they are all stripey.

To get a full sense of the contingency of using race in biomedical patents, it is useful to compare how the PTO and the EPO handled the same patent application for "[t]reatment of hepatitis C in the Asian population with subcutaneous interferon beta."[43] The PTO ultimately granted the race-specific patent while the EPO rejected it for inadequately defining "Asian population."[44] The story of how each office reached its conclusion is a study in contrasts, revealing the possibilities for more rigorous and nuanced examinations of the use of race in patenting.

First, the PTO story. Originally filed in 2003 and assigned to Merck Serono S.A., the patent application related "to the use of recombinant IFN-beta for the production of a medicament for the treatment of HCV [hepatitis C virus] infection by subcutaneous administration to patients of Asian race, which failed to respond to a previous treatment with interferon-alpha . . . ."[45] This race-specific focus was based largely on studies conducted in Japan and Taiwan that observed "differences between patients of Asian and non-Asian origin" in response to IFN-Beta treatments for HCV.[46] Unlike many such applications, this one actually endeavored to define the concepts of "race" and "Asian" as used on the application. Its assertions in these areas, however, are hardly reassuring. It begins by specifying that:

> According to the present invention 'a race' is a population that can be distinguished as a distinct subgroup within a species (e.g. the human species). A race possesses a unique and distinct ensemble of genes, and is identified by the traits (both mental and physical) produced by the genetic ensemble. Members of the same race share distinguishing genetic characteristics, because they share a common genetic ancestry and a consequently similar genetic ensemble.[47]

The assertion here that human races are genetically distinctive entities is deeply problematic, even dangerous in the way it geneticizes race. Two years before this patent was filed, an editorial in *Nature Genetics* clearly stated that "scientists have long been saying that at the genetic level there is more variation between two individuals in the same population than between populations and that there is no biological

43. European Patent Application No. 03755981.2; U.S. Patent No. 7,344,709 (issued Mar. 18, 2008).

44. Merck Serono SA, Decision T 1845/11, at 1 (Tech. Bd. App. 2015).

45. '709 Patent, *supra* note 43, at [57].

46. *Id.* at col. 3 l. 10–13, 43–47.

47. *Id.* at col. 8 l. 12–20 (emphasis added).

basis for 'race.'"[48] This had been the scientific consensus for decades. At least since Richard Lewontin's ground-breaking work on blood group polymorphisms in different groups and races in the 1970s,[49] scientists had understood that race would statistically explain only an exceedingly small portion of genetic variation.

Yet, the patent goes on to cite the work of another renowned geneticist, Luigi Cavalli-Sforza, asserting that based on his "nuclear DNA studies . . . at least 6 human races/populations can be defined: the Caucasoid (which include the European and Indian populations), the African, the Asian, the Arctic, the American Indian, and the Pacific one."[50] Following this citation, the patent goes on to assert: "According to the present invention 'Asian' means any person having origins in any of the original peoples of China, Mongolia, Taiwan, Singapore, Korea, Japan, Vietnam, Cambodia, Laos, Burma, Thailand, Malaysia, Indonesia and Philippines."[51]

On the one hand, it is notable, even laudable, that the patent applicants actually tried to define "race" and "Asian." Most do not. Yet it must be noted that the citation used to support their claim is to a popular science magazine article, not a peer reviewed scientific journal. Moreover, the article cited here makes no direct reference at all to defining six distinct human races/populations, let alone their particular characterization of the category "Asian." The patent appears, rather, to be referring to a graphic in the article, which was titled *Genes, Peoples and Languages*, that specifies "Caucasoid," "African," "Mainland Asian," "Arctic," "American," and "Pacific" but that is further divided into sixteen additional population subgroups without any direct reference to genetics.[52] As the article progresses, we see that it is actually grounded on Cavalli-Sforza's 1988 study of the evolutionary origins of no fewer than "42 world populations."[53] Hardly the distinctive six races asserted in the patent. In fact, Cavalli-Sforza states clearly at the outset of the article that:

> Human populations are sometimes known as ethnic groups, or 'races,' if one likes, although racist misuse of the term has made it rather odious. They are hard to define in a way that is both rigorous and useful because human beings group themselves in a

48. *Genes, Drugs and Race*, 29 NATURE GENETICS 239, 239 (2001).

49. Richard C. Lewontin, *The Apportionment of Human Diversity*, 6 EVOLUTIONARY BIOLOGY 381, 397 (1972).

50. '709 Patent, *supra* note 43, at col. 8 l. 21–26.

51. *Id.* at col. 8 l. 27–31.

52. Luigi Luca Cavalli-Sforza, *Genes, Peoples and Languages*, SCI. AM., Nov. 1991, at 104–05.

53. *Id.* at 109.

> bewildering array of sets, some of them overlapping, all of them in a state of flux. Languages, however, gave us a little help.[54]

As the article progresses, Cavalli-Sforza emphasizes that his study focused on "aboriginal populations . . . that occupied their present territories before the great migratory waves that followed the voyages of discovery in the Renaissance."[55] He goes on to clearly state that "[d]istances between these aboriginal groups cannot be abstracted from the presence or absence of a single inherited trait, or the gene that expresses it, because each group carries practically all the extant human genes. What does vary is the frequency with which the genes appear."[56] So, Cavalli-Sforza's article does not assert that there are six distinct, genetically bounded races. It focuses on particular aboriginal groups and even then clearly asserts that "each group carries practically all the extant human genes."[57] The only thing that varies is the frequency with which certain genes appear. Nonetheless, this is the article that the patent applicant cites to support its assertion that the category "Asian" constitutes "[a] race [that] possesses a unique and distinct ensemble of genes . . . ."[58]

Yet, somehow, the U.S. patent examiner found the reference to Cavalli-Sforza sufficient and the race-specific claims of the patent were never challenged. Perhaps because the applicant actually took the trouble to define "race," the issue of its meaning or the clarity of the term "Asian" never even came up during the patent examination process.[59] And so, the race specific patent issued without objection from the PTO in 2008.[60]

The very same patent application filed before the EPO received very different treatment—specifically with reference to its use of race. In this case, the EPO patent examiner denied the race-specific claim and Merck Serono appealed to the EPO's Technical Board of Appeal.[61] In its 2015 decision, the Board noted that "[t]he sole ground for the refusal" by the patent examining division was that "the present application does not clearly define 'Asian race.'"[62] In reaching this determination, the Board referenced numerous scientific sources, including the

54. *Id.* at 104 (emphasis added).

55. *Id.*

56. *Id.*

57. *Id.*

58. '709 Patent, *supra* note 43, at col. 8 l. 14–15.

59. *Id.* at col. 8 l. 12–20.

60. *Id.* at [45].

61. Merck Serono SA, Decision T 1845/11, at 1 (Tech. Bd. App. 2015).

62. *Id.*

original Cavalli-Sforza article in *Scientific American* cited in the patent application.[63] Notably, it also cited the 2000 *Nature Genetics* editorial questioning the use of racial categories in biomedical contexts.[64]

As summarized by the Board of Appeal, Merck Serono's primary arguments were grounded on assertions that "[c]lassifications by race were routinely made in clinical trials and used by regulatory authorities like the European Medicines Agency (EMEA) or the Food and Drug Administration (FDA)," and "[t]hat self-identification was routinely used in clinical trials . . . ."[65] It further asserted that "[t]he term 'Asian race' was not only clear by itself, but was also fully described in the application, which . . . gave a definition of the term 'Asian' as well as guidance on how the race assignment could be done."[66] The reference to other regulatory authorities such as the EMEA and the FDA is particularly notable, especially because it references the same FDA Guidance on Collection of Racial and Ethnic Data in Clinical Trials that Decode Genetics successfully used to overcome PTO objections to the use of racial categories in its Patent Application No. 12/867,680, "Susceptibility Variants for Lung Cancer," discussed above.[67]

In this case, however, the EPO Board of Appeal took a much closer and more sophisticated look at the claims before it. Setting forth the standard of review, the decision states: "For the clarity requirement of Article 84 EPC to be met**,** the skilled person who reads the claim against the background of his common general knowledge must be able to unambiguously distinguish patients which belong to the Asian race from those which do not."[68] The decision concluded that merely referencing other regulatory agencies was insufficient if these agencies themselves did not provide definitions of sufficient rigor to meet the requirements of defining "Asian" for the purposes of the patent application.[69] It further notes that "[t]he claim itself does not provide a definition of the term 'Asian race', or any indication of the parameters to be used for assigning a patient to the Asian race"; therefore, "[t]he question to be decided is . . . whether or not there exists a clear i.e. unequivocal and generally accepted meaning for the term 'Asian race.'"[70]

63. *Id.* at 1–3 (citing Cavalli-Sforza, *supra* note 52).

64. *Id.* at 6–7 (citing *Census, Race and Science*, 24 Nature Genetics 97 (2000)).

65. *Id.* at 3–4.

66. *Id.* at 4.

67. *Id.* at 2; *see supra* text accompanying notes 36–41 (discussing patent applicant's reliance on FDA regulatory guidance).

68. *Id.* at 5.

69. *Id.* at 8–9.

70. *Id.* at 6.

Of course, the separate "specifications" section of the patent did include the definition of "Asian" as meaning "any person having origins in any of the original peoples of China, Mongolia, Taiwan, Singapore, Korea, Japan, Vietnam, Cambodia, Laos, Burma, Thailand, Malaysia, Indonesia and Philippines."[71] The Board, however, insightfully notes that:

> The expression "having origins" . . . neither excludes mixed origins nor in particular limits the degree of separation from the ancestor providing those origins. Indeed, it would appear that all Europeans have "origins" in the "original peoples" of Asia . . . . However, Europeans are not normally considered to belong to the "Asian race".[72]

Therefore, the Board concludes that "the use of the feature 'having origins' without properly defining the circumstances in which a patient is to be regarded as having those origins gives rise to ambiguity in the definition of 'Asian race' provided by the description."[73]

The Board's decision also discusses at length the 2000 *Nature Genetics* editorial (cited as "document D19") noting that it discloses:

> That issues of, for example, race are, "often associated with poorly defined lay terminology," and that "this is not just a matter of sloppy language, but reflects the imprecise use of racial and ethnic classification in biomedical research." It is therefore concluded in document D19 . . . that "there is no justification, however, to use race as a substitute for other parameters that can be measured, such as genetic variation or differences in metabolism" and "the laudable objective to find means to improve the health conditions for all or for specific populations must not be compromised by the use of race or ethnicity as pseudo-biological variables."[74]

The decision then goes on to quote two additional peer-reviewed scientific articles, noting that "[a]cross all disciplines present, it was agreed that the biologic concept of race is no longer tenable and that race should no longer be considered a valid biological classification";[75] and that "the use of the terms race and ethnicity [. . .] can at times be

71. *Id.* at 11.

72. *Id.*

73. *Id.* at 11–12.

74. *Id.* at 7 (emphasis added) (quoting *Census, Race and Science*, 24 NATURE GENETICS 97, 98 (2000)).

75. *Id.* (emphasis added) (quoting Harold P. Freeman, *The Meaning of Race in Science—Considerations for Cancer Research: Concerns of Special Populations in the National Cancer Program*, 82 CANCER 219, 220 (1998)).

troublesome because of the impreciseness of the definitions, the historical implications of the words, and the lack of any scientific basis for their meaning . . . ."[76] With this close reading of the relevant literature in hand, the Board ultimately concluded that "at the priority date of the present application [2002] the term 'race,' and hence also the term 'Asian race,' had no unequivocal and generally accepted meaning for the skilled person. Accordingly, he could also not determine without ambiguity whether or not a patient belonged to the 'Asian race.'"[77]

This decision is truly remarkable in several respects. It independently examines the concept of race as discussed in relevant literature. While not engaging with the extensive social science literature on racial classification, it does not simply roll over, as did the U.S. patent examiner, in the face of a superficial reference to the Cavalli-Sforza article.

This implies, but admittedly does not definitively establish, that the EPO Board of Appeal had a very different underlying commonsense conception of the nature of race than did the U.S. examiner. As is made clear by the increasing proliferation of racial patents in the United States, most patent examiners—and the PTO in general—can be understood to largely have an underlying presumption that race is, indeed, genetic, scientific evidence to the contrary notwithstanding. This explains the readiness of most patent examiners to unquestioningly accept the use of racial categories in biomedical patents.

As noted above, there are exceptions. But in many respects these exceptions prove the rule, particularly as in the case of Patent Application No. 12/867,680, "Susceptibility Variants for Lung Cancer," where examiner Joseph Dauner withdrew his initial objection after the applicant merely referenced the FDA Guidance on Collecting Racial and Ethnic Data in Clinical Trials.[78] In striking contrast, the EPO, when similarly presented with a reference to the FDA Guidance, placed it in a much broader context of other scientific discussions of race and genetics and came to its own conclusion that the Guidance alone did not sufficiently address its concerns about adequately defining racial categories. The readiness of Dauner to withdraw his objection evidences a readiness to accept—and to perhaps confirm—a basic understanding of race as genetic. In contrast, the EPO Board's response to the guidance, like its response to the Cavalli-Sforza article, was to place it in a larger context and make an independent evaluation of the adequacy of the definition it provided. It clearly does not presume a basic underlying genetic basis for race.

76. *Id.* at 8 (emphasis added) (quoting Frederick P. Rivara & Laurence Finberg, Editorial, *Use of the Terms Race and Ethnicity*, 155 ARCHIVES OF PEDIATRIC & ADOLESCENT MED. 119, 119 (2001)).

77. *Id.*

78. DAUNER, *supra* note 37, at 2.

Conclusion

As we move into a purported era of "precision medicine," it behooves us to consider where race stands as a category of scientific, legal, and commercial interest. Just as the election of Donald Trump to the presidency has driven home to many that we do not live in a post-racial era politically, so too does the continuing proliferation of racial patents indicate that we are also not in a post-racial era scientifically. Yet, it is important to understand that the persistence of race in biomedical patents is neither inevitable nor straightforward. As seen from the several examples examined in depth here, the geneticization of race through the patent process remains a relatively contingent and contested phenomenon. As shown in this Article, patent examiners' responses to the use of racial categories in biomedical patents have varied widely. While in the majority of cases the use of race is not challenged, there are exceptions. Sometimes initial objections have been overcome by simple references to other regulatory authorities, such as the FDA, which appear to be unquestioningly accepted as sufficient to overcome objections. In other cases, a clearly stated objection to the indefiniteness of racial terms has been sufficient to compel an applicant to retreat and withdraw the racial claims. Most powerfully, there stands the example of the EPO, where the examiners undertook an independent review of the literature to critically consider the validity and clarity of racial claims. It is this final example that stands as a beacon to guide future approaches to evaluating race-specific claims in future patents. Let applicants submit such claims, but let them be warned that they must make clear showings of the validity and clarity of their definitions sufficient to overcome the sorts of objections raised by the EPO in its review of the patent for "Treatment of hepatitis C in the Asian population with subcutaneous interferon beta."[79] Though not ideal in all respects, this sort of independent, critically minded review provides a clear and easy-to-follow model of how to begin to approach the review of applications that mix racial and genetic categories to augment legal protection for their biomedical inventions.

79. Merck Serono SA, Decision T 1845/11 (Tech. Bd. App. 2015).