

Semiconductor Chips and Stem Cells: New Wine for New Bottles?¹

(Working Draft, not for publication)

Abstract

This paper provides a contrast between semiconductor technology and the economics surrounding the semiconductor industry and stem-cell technology and its surrounding economics, to make the case for *sui generis* intellectual property protection for stem cells. I will establish that just as semiconductors failed to meet the social bargains of copyright and patent in the early 80's, stem cell technology presently fails to meet the patent bargain requirements of novelty, non-obviousness and utility. Nevertheless, like semiconductors, the high cost of stem cell research and development, coupled with the need to sustain continued economic growth of the biotechnology industry, mandates that Congress provide some level of exclusive rights to bridge the existing gap. *Sui generis* IP protection for stem cells would preserve the incentive to continue innovation. However, as illustrated in the semiconductor industry, any *sui generis* protection for stem cells must include limitations that address the need to provide an appropriate level of public access to facilitate efficient and effective downstream research in the area of regenerative medicine, thereby enriching the public domain.

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I. Introduction

“Inventions in most, if not all instances rely upon ‘building blocks’ long since uncovered.....”²

“Congress can be trusted to consider issues arising from technological development and to craft appropriate solutions conferring statutory protection on the creative product of new technologies.”³

Stem cells are one of today’s basic biological building blocks and are at the core of regenerative medicine research. Stem cells exist at the earliest stage of biological development and are valuable due to their capability to grow or “regenerate” into a variety of cell types. The regenerative capability of stem cells is useful for downstream research on how to replace defective tissue and organs associated with a host of diseases. For example, replacing defective pancreatic cell tissue could lead to a cure for diabetes, while making brain cells that secrete dopamine may lead to a cure for Parkinson’s disease. Adult stem cells are ‘multipotent’ and can develop into different cells within a basic cell type. For example, adult bone marrow stem cells can develop into numerous blood cell types and have been used to treat leukemia and lymphoma. However, even more powerful than adult stem cells are embryonic stem cells which come from the inner cell mass of a blastocyst.⁴ Unlike adult stem cells, embryonic stem cells are pluripotent, and thus capable of developing into any organ or tissue type, except sperm and egg cells.⁵ The pluripotent nature of embryonic cells makes them a preferred upstream research tool since they enable scientists to explore treatment options for a wider range of human diseases and are not as limited in their regenerative capacity as adult stem cells.⁶

² KSR v. Teleflex, No. 04-1350 at pp. 15 (April 30, 2007)

³ Kastenmemeier and Remington, “The Semiconductor Chip Protection Act of 1984: A Swamp or Firm Ground”, 70 Minn. L. Rev. 417, 467 (1985)

⁴ A blastocyst is a 4 day old fertilized egg. See Jessica Reaves “The Great Debate over Stem Cell Research”, www.time.com/time/health/article/0,8599,167245,00.html

⁵ Cite Biotech text, and note Embryonic stem cells develop 5-14 days after the egg is fertilized and found in the interior of the blastocyst. There are more than 200 cell types in the adult body and embryonic stem cells (ESC’s) can develop into any of these cell types when given the proper stimulation.

⁶ Unfortunately, most experts estimate that we are at least 10 years from implementing safe and effective stem cell therapy. See e.g. Dr. Ann L. Boyd, presentation “Human Stem Cell Research History and Development”, Presented at the 2007 Biotechnology Symposium at NCCU.

Unfortunately, embryonic stem cells are presently caught in a web of moral and intellectual property conflict. Many pro-life advocates find it morally offensive to use embryos from in vitro fertilization to generate human embryonic stem cell lines for research purposes.⁷ They argue that the moral costs of taking a life, outweigh any therapeutic benefits from stem cell therapy.⁸ The successful lobbying efforts of pro-life advocates resulted in the Federal Government's ban on the use of federal funding for the research and development of new embryonic stem cell lines.⁹ Currently, federal funding is limited to stem cell lines in existence prior to the ban.¹⁰ Since there is an insufficient amount of private capital to bridge the federal funding gap, some states have created their own funding schemes to support the advancement of stem cell research and regenerative medicine.¹¹

The controversy surrounding embryonic stem cells goes beyond ethical and moral issues. The patenting of human embryonic stem cells remains at the center of a hotly contested debate on how to give the public greater access to this technology, while simultaneously providing the level of exclusive rights needed to preserve the incentive to continue innovation. On one side of the debate is the Wisconsin Alumni Research Foundation, assignees of the three Thompson stem cell patents, which together claim the exclusive rights to all human embryonic stem cells and methods for creating these stem cell lines.¹² On the other side, is the Foundation for Taxpayer and Consumer Rights ("FTCR") and the Public Patent Foundation

⁷ Despite the fact that the frozen embryos used in research were generated in fertility clinics and were no longer needed by the particular clients. Aborted fetuses are an alternative source of stem cells, but as would be imagined this is more offensive to pro-life advocates than obtaining cells from stored in the in-vitro fertilization clinics. Scientists are currently exploring future Therapeutic Cloning -somatic cell nuclear transfer "SCNT" which allows scientist to produce embryonic stem cells without using sperm to fertilize the egg, but may still raise moral issues for ultra conservative pro life advocates who view this as 'embryo' harvesting and the taking of life...SAR NOTE..CHECK ON PRESENT STATUS OF SCNT RESEARCH.

⁸ Reaves, supra note 2 at pp. 4

⁹ Cite...Not everyone in the Bush administration favors a ban on embryonic stem cell research. HHS secretary Tommy Thompson wanted to continue federal funding for research on human stem cells. Also, some conservative Senators such as Orrin Hatch favor continued research funding.

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¹¹ See, e.g. 7/31/2007 Michael E Mirales Jr., "States as Innovation Laboratories: California, Patents, and Stem Cell Technology", 28 *Cardozo L. Rev.* 1133 (2006) (Discussing California's 72 billion dollar investment in stem cell research and formation of the California Institute of Regenerative Medicine. The author applauds California's attempt to have a funding scheme that overcomes the flaws of the Baye-Dole Act, the existing federal funding scheme for scientific research.). Wisconsin and New Jersey are also developing their own funding schemes to promote stem cell research and the growth of the bio-technology industry in their respective states. (cite).

¹² The Thompson patents are: U.S. Pat # 5,843, 780 (1998), U.S. Pat. # 6,200,806 (2001) and U.S. Patent #7,029,813 (2006) for "primate embryonic stem cells").

("PUBPAT"), who jointly filed petitions for reexamination of the three WARF human embryonic stem cell patents and argue that the embryonic stem cell lines belong in the public domain, since they lack novelty and are obvious in light of existing prior art.¹³ Both FTCR and PUBPAT view the Thompson patents as "outrageous, overreaching" and an attempt to gain an unlawful monopoly on preexisting research that should remain in the public domain.¹⁴

On March 31, 2007, the PTO agreed with PUBPAT and rendered a preliminary finding that the embryonic stem cells lines and methods disclosed in the three Thompson patents were unpatentable as both obvious and lacking novelty.¹⁵ On May 31st, WARF narrowed its claims in response to the PTO findings, limiting their claims to 'pre-implantation embryos'.¹⁶ The response also included arguments that the lines were indeed both non-obvious and novel. On June 29th, 2007, the consumer groups filed comments to WARF's response.¹⁷ Both sides argued that the non-obviousness case recently decided by the Supreme Court, *KSR v. Teleflex*, supported their position.¹⁸ WARF argued that stem cell technology fell within the 'unpredictable arts' distinguished by the Court and requiring something other than hindsight knowledge to establish obviousness.¹⁹ The Consumer Groups countered that stem cell technology falls squarely within the scope of *KSR* that allows for more than the 'rigid' teaching, suggestion, motivation test to evaluate obviousness. Thus, they argue, the *KSR* decision strengthens the PTO's rejection of the Thompson patents on obviousness

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¹⁴ See Pubpat website www.pubpat.org. There are also a host of scholars and scientist that caution against granting patent protection to upstream research tools such as stem cells and gene sequences...cite 'anticommons' scholars, Davis essential facility note and Rose compulsory licensing article.

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¹⁶ Thus arguably, stem cells generated by somatic nuclear cloning and other therapeutic cloning methods would likely fall outside the scope of the Thompson claims. (Cite BNA and PUBPAT <http://www.pubpat.org/stemcellcomments.htm>)

¹⁷ Because the '780 and '806 reexamination proceedings were ex-parte under the older provisions of Sections 302-307 of the Patent Act, the consumer groups were only allowed to file a public comment for the '913 patent reexamination response, which was the only reexamination initiated under the newer 'inter-partes' reexamination provisions of Sections 311-318 of the Act. See BNA Patent, Trademark and Copyright Daily, Friday July 6, 2007 "Parties Respond to the PTO's Revocation of the Three Embryonic Cell Patents.

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¹⁹ WARF contrasted the unpredictable nature of stem cells and the vast differences between primate/human stem cells and the prior arts mouse ES cells and embryonic germ (EG) cells., with the basic predictable and well-established mechanical arts technology of throttle pedal at issue in *KSR*. Cite response and PTCJ

grounds.²⁰ The PTO should issue its final determination by the end of the year.

Meanwhile, embryonic stem cells are not the only type of stem cells whose patentability is being called into question. On July 9, 2007, the Federal Circuit held that two Patents covering the collection, cryopreservation and use of stem cells from umbilical cord blood were invalid as obvious in light of existing prior art.²¹ Interestingly, the court found the patents invalid, despite their being upheld in a prior reexamination.²²

Although no one can predict the final outcome of the reexamination of the WARF embryonic stem cell patents, the dispute provides motivation to evaluate whether embryonic stem cells and stem cells in general, are properly placed within the patent intellectual property regime. Several scholars are presently debating this issue. In addition to non-obviousness and novelty problems, scholars have raised anti-trust, utility, morality and the need for greater access as grounds for removing stem cell technology from patent law, or at least adding limitations to the Patent Act for stem cells.²³ However, removing stem cells from the patent regime may prove disastrous to the bio-technology industry which relies on the ability to create patent portfolios as a means of attracting venture capital, generating licensing revenue and covering the cost of continued research and development.²⁴

So, if stem cells are not patentable, is there an alternative means of providing intellectual property protection for stem cells that would preserve the incentive to continue research and innovation in this area, while addressing the needs of the public domain? In other words, is this one of the rare occasions for Congress to step in and offer some type of hybrid *sui generis* intellectual property protection for stem cells which would strike the appropriate balance between innovation and access, despite stem cells failure to meet the Patent Social Bargain of requiring novelty, concrete

²⁰ Specifically, the court rejected the Federal Circuit's rigid application of the "TSM", teaching suggestion, motivation test and held that at best it is a 'helpful insight' rather than a rigid formula to be applied by courts (add pinpoint cites).

²¹ *PharmaStem Therapeutics Inc. v. Via-Cell, Inc.*, Fed. Cir. , No. 05-1490.

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²³ SAR cite and give synopsis of various articles

²⁴ Cite Genron/Warf licensing arrangements and proposed CIRM licensing patent pooling arrangement

utility and non-obviousness in exchange for exclusive rights?²⁵ Are stem cells a new type of intellectual property ‘wine’ that needs a new and different type of intellectual property ‘bottle’ for protection?²⁶ What factors should Congress consider when making this determination? In the past, Congress has taken a dim view of *sui generis* IP protection and refused to create *sui generis* statutes for computer programs and databases.²⁷ Indeed, there are only two instances of Congress providing *sui generis* intellectual property protection in the past 100 years. They are the Semiconductor Chip Protection Act of 1984 (“SCPA”) and the Boat Hull Protection Act which was passed as part of the Digital Millennium Copyright Act of 1995. Of the two, the debate surrounding semiconductors and the passing of the SCPA provides the greatest guidance and parallels to the current stem cell dilemma.

Like stem cells, semiconductors are the upstream “building blocks” for computers and information technology. Also, like the biotechnology industry, the semiconductor industry is one of the most research and development intensive industries in the United States.²⁸ Semiconductors are comprised of semiconductor material (typically silicon) containing layers of electronic switches.²⁹ Early chip designs were of discrete semiconductors containing individual circuits performing a single function which effects the flow of electrical current, e.g. a transistor which amplifies electrical signals. Later chip designs were comprised of complex integrated circuits containing

²⁵ The Intellectual Property Clause of the U.S. Constitution is at the heart of the Social Bargains of both Patent and Copyright Law, it mandates that in order to promote progress in Science and the Useful Arts, Congress provide exclusive rights for ‘limited times’ to authors and inventors. The Patent Act enforces this mandated Bargain, by requiring novelty (first inventor), non-obviousness, utility and an enabling disclosure before granting the limited 20 year exclusive patent right. In exchange for the Patent Right, the inventor dedicates her invention to the public domain at the end of the patent term. Thus both society and the patentee reap benefits from the patent regime. See U.S. Const. Article 1, Cl8,. Section 8. See also, Rose, monopolophobia article and Samuelson, “Creating a New Kind of Intellectual Property: Applying the Lessons of the Chip Law to Computer Programs”, 70 Minn. Law Review 471, 512 (“Similarly, the social bargain inherent in patent law also involves an exchange. Society grants the inventor a certain set of exclusive rights, primarily a seventeen-year term of control over the making and distribution of the invention, in return for disclosure of the elements of the invention and the eventual right of the public to practice freely the art the patent teaches.”).

²⁶ I must give John Perry Barlow credit for this phrase ‘new wine for a new bottle’ since he first coined it in reference to internet technology creating a new wine for copyrightable subject matter which needed a ‘new bottle’ since it was a misfit for the existing Copyright Law Bargain (cite)

²⁷ Cite Pam Samuelson and Congressional history

²⁸ Semiconductor Industry Association (1993) *Databook (IA, San Jose, CA) pp. 41; also cite Sematech paper discussing formation of semiconductor research consortium in 1987. See also, K-Remington at pp. 6, (“Semiconductors are at the center of information society).*

²⁹ See U.S. Industry Profile semiconductors and Related Devices, Thompson and Gale 7/2/2007

thousands of transistors and capacitors placed on a tiny rectangle of silicon. Integrated circuits can serve as computer memory components (e.g. Read only memory and Random Access Memory), logic devices (performing several specialized computer functions on a single chip) or a combination of memory and logic devices.³⁰ Today, semiconductors are the back-bone electronics for a host of devices, including computers, appliances and automobiles.³¹

Semiconductor chips are manufactured by laying a stencil or “mask” on top of a layer of semiconductive material, then etching or imprinting circuit patterns on each layer. Initially, the original or ‘inventive’ portion of a semiconductor chip was the topography or “mask” of the chip. Semiconductor designers aggressively sought both patent and copyright protection for chip designs since designs were both costly (over 80 million dollars) and time consuming. Unfortunately, after the first chip design was patented, later designs were often rejected by the PTO as being obvious in light of the prior art.³² Designers then sought to register semiconductor chip designs as ‘mask works’ under the Copyright Act. They enjoyed limited success, but ultimately, the Copyright Office could not resolve the conflict between protecting mask works and Section 101’s express prohibition against protecting the “utilitarian” aspect of pictorial graphic and sculptural works.³³ Since the early chip designs were easy to reverse engineer and relatively inexpensive to duplicate (around \$50K), chip piracy became rampant and the Semiconductor industry lobbied Congress for some type of “sui-generis” protection for chip designs to bridge the existing gap in intellectual property protection and preserve their incentive to continue innovation.

Like the current stem cell debate, there were differing views on how Congress could bridge the gap in intellectual property protection for

³⁰ Id.

³¹ Insert cite

³² See Riseberg, 5 years without infringement Litigation under the Semiconductor Act, 1990 Wisc. L. Rev. 241, 251-252 (1990), (“While patent law can protect electronic circuitry or an improved process of manufacture-topography of such layout[chip design] do not meet non-obvious standards....) Ultimately, by the late 80’s and early 90’s when semiconductor chips became part of integrated circuits, patents were more frequently granted for integrated circuitry design and processes for manufacturing these chips. See also, Chesser and Riasch.

³³ Cite Section 101 and note that mask works failed the separability requirement of Section 101 since they were neither physically or conceptually separable from the electronic utility of the chip itself. Cite Samuelson, K-R and other semiconductor articles. The utilitarian exclusion in copyright exist to avoid the Copyright Act to artificially extend the term of a ‘useful’ object beyond the 20 year term provided for under the Patent Act.

semiconductors, without impeding downstream research and development in information technology.³⁴ Intel and other large chip designers argued that they needed relatively broad exclusive rights to effectively combat chip piracy and continue chip innovation.³⁵ Smaller chip designers and researchers conceded that *sui generis* protection was necessary, but countered that any sui-generis legislation must include a comprehensive reverse engineering limitation which would allow for copying of a registered chip design to facilitate downstream product improvements.³⁶

In the end, both sides reached a ‘meeting of the minds’ and Congress was able to pass the 1984 Semiconductor Chip Protection Act (“SCPA”).³⁷ The Act contained a range of exclusive rights and limitations tailored to meet the incentive and access issues uniquely relating to semiconductors. Although the SCPA was placed in the Copyright Act, it was viewed as stand-alone, hybrid *sui generis* protection for semiconductor chip designs since it borrowed from both patent and copyright law.³⁸ For example, the SCPA contained its own unique set of exclusive rights to make, import and distribute chips embodying mask work designs.³⁹ Also, rather than the 17 year term of exclusivity enjoyed by patentable subject matter, or the life of the author plus 50 term that existed for copyright, chip designs enjoyed a 10 year limited term of protection.⁴⁰ This term was viewed as commensurate with the typical 2-5 year commercial life for a chip design.⁴¹ Unlike the Copyright Act, there was no derivative work right in the SCPA. Instead, the Act allowed for ‘reverse engineering’ a protected chip design as long as the new chip design was a ‘significant change’ from the protected chip.⁴² Like the Patent Act, the SCPA contained a statutory bar provision requiring a chip designer to register within 2 years of the first commercial exploitation of the chip, or lose protection under the SCPA.⁴³

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³⁸ SAR note that although intending to be a ‘sui-generis’ hybrid of patent and copyright, some scholars argue that one of the flaws of the SPCA was that it placed in the copyright act and contained too broad a reverse engineering limitation to be effective. (cite Chesser and others)

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⁴³ SAR-add that complex chip designs, coupled with the formation of the Federal Circuit and relaxed non-obviousness requirement led to increased strategic patenting of chip designs as an alternative to protection under the SCPA. Cite Bronwyn H. Hall and Marie Ham, “Patent Paradox Revisited: Determinants of Patenting in the US Semiconductor Industry, 1980-94” Working Paper No. CPC99-05 Competition Policy

This article makes a case for *sui generis* IP protection for stem cells by contrasting semiconductor technology and why it warranted *sui generis* protection to bridge the intellectual property gap, with the current economic and access issues surrounding stem cell technology and why they too, might benefit from a *sui generis* IP statute.⁴⁴ First, I will first take a walk back in history and review how the semiconductor industry was able to persuade Congress to create *sui generis* intellectual property protection for semiconductors. I will outline and analyze the 4 part test promulgated by Congressman Robert Kastenmeier and scholar Michael J. Remington to substantiate why *sui generis* IP protection was the only viable mechanism to achieve the Constitutional mandate of providing both an incentive to innovate and enhancement of the public domain.⁴⁵ I will also discuss Professor Pamela Samuelson's arguments on why semiconductors failed to meet either the Patent or Copyright bargain, but yet, like computer programs, warranted *sui generis* intellectual property protection to bridge the intellectual property gap.⁴⁶

Next, I will evaluate how successful the SCPA was in contributing to the growth of the semi-conductor industry, as well as its overall effectiveness. Despite the fact that most semiconductor design corporations registered their chip designs under the SCPA, there is only one recorded case of semiconductor chip infringement under this statute. Some scholars cite this as evidence of the statute's ineffectiveness and attribute the reluctance to

Center, University of California, Berkeley (discussing use of stem cell patent portfolios as a tool for licensing leverage, e.g. obtaining better terms for cross licensing agreements (see pp. 8); see also Rauch, "The Evolution of Our Times: The Semiconductor Chip Protection Act of 1984 and the Evolution of the Semiconductor Industry," 3 Fordham Ent. Media &Intell Prop. L.F. 403 (1993);

⁴⁴ As one might expect, I am not the first scholar to contrast technologies to make the case for 'sui-generis' IP protection. In her 1985 seminal article, Professor Pamela Samuelson contrasted semiconductors with computer programs to make an excellent case for sui-generis protection for computer programs.

⁴⁵ See Kastenmeier and Remington, "The Semiconductor Chip Protection Act of 1984: A Swamp or Firm Ground", 70 Minn. L. Rev. 417, 440-442 (1985) Interestingly, the authors propose applying their test to any proposed intellectual property legislation, including changes to patent law. The four part test includes: First, establishing that the change [new legislation] fits "harmoniously within the legal framework without violating existing principles or concepts"; Second, the new interest must be clearly defined as to what it is and is not; Third, a clear cost-benefit analysis must be presented; and Fourth, advocates must demonstrate how the new intellectual property right will enrich or enhance the public domain. Interestingly, the authors distinguish that Congress did not physically apply their 4-factor test before passing the SCPA, but that their factors were inherent in the legislative discussions. The article goes on to demonstrate how the SCPA clearly satisfies the 4-part test. Overtime, the test has been identified as the "Kastenmeier-Remington 4 part test for Enactment of Sui Generis Legislation". See .e.g. Pamela Samuelson, Letter to Rep. Howard Coble, dated 10/23/97 re: Tyson/Sherry Report (arguing that H.R. 2652, Collections of Information Antipiracy Act (proposed database protection legislation failed to meet the 4 part K-R sui-generis test).

⁴⁶ Cite Rauch, Riseberg and Chesser

litigate to ambiguities in the statutory language and an overly broad reverse engineering exception.⁴⁷ Others argue that international trade and exponential advancements in semiconductor technology rendered the SCPA obsolete.⁴⁸ However, there are scholars who advocate that the SCPA was indeed effective legislation which contributed to the growth of the semiconductor industry and positively impacted international trade.⁴⁹ I agree with these scholars and Professors Pamela Samuelson and Suzanne Scotchmer who posit that since the SCPA probably contributed to the rise in second-source licensing agreements and led to a reduction in chip piracy, it had an overall beneficial effect on the market.⁵⁰

After illustrating the overall positive impact that the SCPA had on the semiconductor industry, I will begin applying the *sui generis* analysis to stem cell technology. First, I will apply the Samuelson “patent bargain failure” analysis to establish that as long as stem cell inventions lack obviousness and have questionable specific utility, they cannot benefit from the patent bargain and we must look to alternative legislation to preserve the incentive to innovate. Second, I will attempt to apply the lessons learned from the SCPA to outline what exclusive rights and limitations a model stem cell statute should contain to provide the ‘wings’ effect of enhancing research and development in the area of regenerative medicine, while simultaneously enriching the public domain. I advocate adopting stem cell legislation that is more ‘patent-like’ in scope than the SCPA, but like the SCPA, provides a more limited term of exclusive rights. The legislation should also mirror the SCPA and include some type of limitation, such as a well-defined experimental use or compulsory licensing provision which allows for access to stem cells during their term of exclusivity for parallel upstream scientific research and certain downstream research and development. Finally, I will apply the 4-part Kastenmeier-Remington test for the enactment of *sui generis* legislation to upstream stem cell technology to substantiate that it meets the exceptional standards for Congress to deviate from Patent Law, and provide hybrid *sui generis* protection for stem cells.

⁴⁷ Cite Rauch

⁴⁸ Cite Kasch, The Semiconductor Chip Protection Act, Past, Present and Future, 7 High Tech. L. J. 71 (1993)

⁴⁹ Cite Rodomsky

⁵⁰ Cite Samuelson and Scotchmer, “The Law and Economics of Reverse Engineering”, 111 Yale L.J. (2002); see also Thomson and Gale, U.S. Industry Profile, Semiconductors and related devices (SIC 3674) “The semiconductor industry was one of the fastest growing sectors in the U.S. economy between 1987-1996, when it grew from the 17th largest industry in the U.S. to the largest as measured by its contribution to the U.S. Gross Domestic Product.” At pp. 2 and 4

Conclusion

Since stem cell technology fails to meet the Patent Social Bargain requirements of novelty, non-obviousness and utility, we must explore alternative *sui generis* IP legislation to bridge the gap. Any proposed legislation must preserve the incentive to innovate, while enhancing the public domain, rather than creating an 'anti-commons'. A well balanced 'petit patent' for upstream stem cell inventions should have the same 'wings effect' that the SCPA had on the semiconductor industry and facilitate continued research in the much-needed area of stem cell therapy.