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Infringement of Novartis' Cancer Drug Using Genomic  
Architectures of Legal Literature Based on UK Intellectual  
Property Law**

*Zharama M. Llarena*



# Shepard's Validation of Antitrust Relief Framework on Patent Infringement of Novartis' Cancer Drug Using Genomic Architectures of Legal Literature Based on UK Intellectual Property Law

 **Zharama M. Llarena**<sup>1\*</sup>

<sup>1</sup>Doctor of Jurisprudence student, School of Law and Justice, University of Southern Queensland  
Toowoomba, Australia  
WOS Researcher ID: H-5086-2016



## Article History

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## Abstract

**Purpose:** Comparative law is designed for alignment of constitutional law with other countries advocating public welfare and safety. The United States has an Intellectual Property provision under U.S. Fair Clause using their constitution as pre-emptive doctrine. The aim of this paper is to evaluate the applicability of UK Intellectual Property Law based on their complexed policies on Artificial Intelligence. Hence, it leads to problem statements questioning: (1) the eligibility of matters of facts did not meet UK IP Law; (2) the standard for evidence towards invention using Artificial Intelligence does not conform with UK IP Law; (3) Liability in AI patent infringement is not subsistent in UK IP Law; and (4) AI's compliance is not subject for responsibility under creativity and non-obviousness criteria.

**Methodology:** The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement promotes the public welfare and safety under constitutional laws. India, as a member, is obliged to comply with the standard of evidence in patentability under World Trade Organization (WTO). The study employs comparative contextual assessment using Novartis' case as trial proceedings for disclosing theoretical framework vital to socio-legal integration of WTO principles.

**Findings:** The World Trade Organization is a committee responsible to advocate business law. Invention for marketability of patent product has its own complexed policy to comply for acceptance of an Intellectual Property creation. Constitutional law is designed to be made comparable with other countries promoting monetary success of their nation exhibiting economic progress in industrial and technological advancements. Hence, authorless works marking artificial intelligence towards public health and safety must be done in lack of any dedication to human connections resulting to immersion of their "new" product as a work of an art making non-obviousness skills to people as part of common logic and interests, hence, a product of convenience.

**Recommendations:** WTO is an intergovernmental task force important to implement constitutional laws comparable to other countries resulting to theory integration of socio-legal aspects based on trade-related principles. Hence, the advocacy of business ethics is a highly acknowledged means of making the lives of people to be technologically advanced with convenience, thus, inventions should be made affordable for public access.

**Keywords:** *Patent Law, Artificial Intelligence, Copyright, Intellectual Property, Constitutional Law*

## 1.0 INTRODUCTION

The American government acknowledged legal issues and gathered proposals designed to resolve antitrust cases through compulsory licensing as structural relief on patents and trademarks. Competition is crucial in advocating monetary profits from controlled business endeavors; hence, assurance must be secured against possible legal damages. Thus, antitrust laws are available and serve as reliable enforcement in facilitating payments as remedy to all types of legal harms. In contrary, as the government requires the company to apply for patents or trademarks, arguments spawned a concern pertaining to research incentives and client demands that may create a legal problem on their policy. According to United States Supreme Court, during an antitrust case, the judicial goal is to pay for the disclosed market competition based on investigation purposes. Hence, the relief is characterized as efficient remedy to violations resulting to competition restoration.

In relation to this goal, the Federal Trade Commission and Justice Department are known basically to promote treatment orders through prohibition of continued usage of confirmed illegal practices. Moreover, they have the legal authority to execute restoration of broader competition vital to secure structural remedy. The decisions made by the government for the relief is designed for redressing violations and investigating disclosed competition in market and must be perceived as carte blanche powers. Its authority is restricted to specified harms practiced essential to effectively terminate the proven illegal offenses and restore functional competition. Furthermore, the compensation per case should be based on least severe alternative treatment as legally evaluated matters of particular facts. Hence, the relief being sought must be based on purpose for countervailing proven unlawful practices and not to be ordered as a type of punishment. [1]

### Matters of Facts

Novartis Pharmaceuticals manufactured the drug Glivec under the World Health Organization non-proprietary name of Imatinib. This drug is known to be a derivative of N-phenyl-2-pyrimidineamine and Jurg Zimmerman, who originally created this type of medicine as a medicinal chemist, also invented a number of its other derivatives. All of these derivatives possess anti-cancer properties, hence, designed to inhibit particular protein enzymes for the appropriate treatment of warm-blooded animals. Thus, the United States (US) Patent Office documented these results as patent registration dated 28 April 1994 and granted Imatinib a patent in 1996.

Novartis extended further research discovering that the Imatinib beta crystalline form is characterized to have stable property. Although the U.S. Patent Office initiated opposition to this matter, Novartis was granted a patent. In 1998, using the same product, the drug company extended a patent application in India. However, as India gained full compliance with Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, it was only acknowledged in 2005.

The Novartis' patent application stated that the reference for the found beta crystalline characters claimed to be an imaginative step conceptualizing a two-stage process of invention which involves the injection of a definite beta crystals amount into the Imatinib base form. The particular claims in the Imatinib beta crystalline functions are:

- (a) Its structure creates flow properties that are beneficial in action mechanism;
- (b) Its design offers better stability based on thermodynamics; and
- (c) Its purpose has lower hydroscopic character than Imatinib alpha crystals.

These claimed properties of Imatinib beta crystalline structure made the drug to be considered as “new” and the alleged higher quality is based on improved storage capacity, easier process, and better compatibility of methane sulfonic acid with formula I compound, tandem with storage and manufacture benefits.

Chennai Patents Office made and considered two crucial advancements prior to the patent application. First, there was an amendment on the Patents Act resulting to introduction of section 3(d). Second, it gained attraction with five pre-grant dissents prior to the consideration of patent application. The most reasonable arguments are sourced from market competition based on the mere fact that the claimed invention had been expected, apparent, and brought difficulty with section 3(d) of the Patents Act.

The Assistant Controller of Patents and Designs evaluated the subject matter pertaining to the patentability of Imatinib beta crystalline structure and rejected the application based on lack of novelty as expected on the argument of previous publication. Furthermore, its failed novelty did not meet the acid test standard running afoul with section 3(d). [2]

### **Matters of Law**

Novartis took an appeal after the rejection of the Patents and Designs’ Assistant Controller and requested for re-evaluation to the Madras High Court based on their dissent that section 3(d) was deemed to be unconstitutional since they assert that they complied with TRIPS Agreement. During this case, Intellectual Property Appellate Body (IPAB) has not yet been created. Subsequent to the IPAB formation, the questions of law was referred to them by the High Court in Australia. In spite of the arguments of Novartis to favor them and reverse the previous decision based on ruling of novelty and patentability of obviousness, the IPAB decided to reject the patent claim due to diversion from section 3(d) of the Act since this provision enforces that the claimed invention must be of high standard and clarifies that India has a separate patent law based on their provided provisions.

Moreover, IPAB further investigated and concluded that section 3(d) specifically targets drugs as pharmaceutical substances. The IPAB emphasized the Novartis’ pricing policy of having “exclusive” competition rights over Glivec with argued monetary monthly earnings at 120,000 Indian Rupees per needed dose, and refused the patentability of the drug product based on section 3(d) violation of the Act since granting of the patent must be prohibited on this particular imaginative exploitation that would lead to social confusion belonging to poor quality category of public right. Nevertheless, Novartis sought an appeal with IPAB decision and requested for evaluation of Supreme Court in India. Although, there was an initial hesitation to acknowledge the appeal, the Supreme Court accepted to hear the appeal based on constitutional rights and its accompanied deferments. [2]

### **Question Development**

Under transformative technology, artificial intelligence (AI) is revolutionizing the lives of many people in various aspects. Comparable to UK Intellectual Property Office (IPO), their government enforces their plan of making AI as top priority promoting technology and restraining its powers. Hence, Artificial Intelligence and Intellectual Property: Copyright and Patents relatively opens for consultation dated 29 October 2021 and 7 January 2022. There are three specified areas being reviewed by UK Intellectual Property Office (IPO) as “evidence and invention”, namely: (1) Copyright protection under computer-generated works in the absence of human author for UK

protection of 50 years; (2) Text and data mining (TDM) licensing with exceptions to copyright; and (3) Patent validation for AI system of invention. The Consultation uses a structured format, the existing evidence of text serves as an authentic submission reproduction. Hence, the fair use policy option of neutral technology, as an exception to open-ended user, is unavailable in this invention format. [3]

The higher authority grants a natural person(s) to enjoy a privilege as their copyright protection of Intellectual Property Rights' brand serving as a legal right. Based on World Intellectual Property Organization (WIPO), Intellectual property (IP) is defined as human mind creations consisting of not only literary pieces, inventions, and artistic works, but also names, symbols, and images used in market competition. The incentive in competitiveness creates obviousness in innovation and creativity as exclusive IP rights. Furthermore, the legal system in IP provides people a monetary benefit to creators as basic recognition of their invention under protection rights specified under Article 27 of the Human Rights' Universal Declaration. In addition to that, Article 27 states that authors of scientific inventions, literary, and artistic creations are protected with moral benefits based on their generated material of interests as constitutional right. [4]

AI is crucial enough for promoting advanced technologies resulting to groundbreaking effects as an edge in human communication, hence, making all people to understand the language. However, its technological developments are also mentioned to distort various copyright frameworks such as several US patent law particulars. In support of the U.S. patent law, its five main criteria that authenticate patentability of subject-matter, such as utility, eligibility, novelty, enablement, and non-obviousness, has demonstrated technological resilience towards social change. Insufficiencies in AI preparation resulting to collisions may run afoul with its main goals implicating economic, social and ethical disruptions. [5]

The pharmaceutical industry in India is known to be the world's 3<sup>rd</sup> largest pertaining to volume and ranked 14<sup>th</sup> based on value. Yusuf Hamied, the Indian chairman of CIPLA pharmaceutical company, stated that their country is accountable for the sales growth of drug-manufacturing services with apparent U.S. Food and Drug Administration approval than any other territories beyond United States' jurisdiction. Since 2005, India has been fully compliant in their obligation with benefits to Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement as it was enforced according to patent law amendments meeting global standards, thus, India stands as major supplier of affordable medicines worldwide. [6]

Although United States welcome invention under U.S. Fair Clause under their own constitution, questions are raised whether it undermines other Intellectual Property Rights based on constitutional laws. From this paper, the following questions are developed as problem statements:

- (1)The matters of fact are ineligible in compliance with AI technologies under UK Intellectual Property (IP) Law;
- (2)The matters of law do not meet with the invention standard using Artificial Intelligence in patentability under UK IP Law;
- (3)Liability in AI patent infringement is not apparent under UK IP Law; and
- (4)AI's obligation did not comply under creativity and non-obviousness criteria under UK IP Law.



## **2.0 METHODOLOGY**

### **Trade Agreement as Integrating Theory of Socio-Legal Research**

For more than 30 years, the Indian government had freely kept their drug production practice to manufacture and market medicines formulated by foreign companies at a cheaper cost and disallowed patented pharmaceutical inventions to trade in their country. As India became a member of the World Trade Organization (WTO) in 1995, they were obliged to amend their patent laws within a transition period of ten (10) years. India's revision for global standards of patent law followed compliance with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The purpose of TRIPS serves as a verification and validation of the minimum standards set by WTO for intellectual property protection. Hence, this Patents Act acknowledged India's technological, developmental, socio-economic, and public interest necessities.

The Swiss drug manufacturer, Novartis, created Glivec (imatinib mesylate) for the treatment of Gastrointestinal Stromal Tumours (GIST) and Chronic Myeloid Leukemia (CML) as a patent design in 35 countries worldwide. Based on the study of Lee, Glivec is found to be more effective since it efficiently targets specified cancer proteins of about ten times than conventional interferon treatment. Similarly, the drug does not provide a permanent remedy against cancer, just a traditional termination of its early proliferation stage, hence, taken to be a lifelong treatment. Furthermore, Indian government does not render private health insurance to majority of its people, hence, they promote cheaper medicines for continuous supply and access to effective treatment, thus, the pricing of Glivec plays a critical source for market competition. Hence, a significant price gap is apparent between Glivec and its cheaper counterpart amounting to \$5,000 in the U.S. in comparison of its generic price of USD \$200 in India. [6]

### **Patent Law (Comparative Contextual Analysis of Trial Proceedings)**

The 1970 Patents Act was revised in 2005 requiring that inventions must be "new" inventive step that cannot be predicted involving industrial utilization. Hence, it should demonstrate technical advancements in comparison with current knowledge that would highly result to economic significance. Moreover, the invention must exhibit a feature known as non-obviousness creating commonness to all people to be skilled in the art. [2]

According to section 3(d) of the Act, the following are not considered invention:

The known substance discovery is not a mere new form, thus, not original, resulting to non-improvement in enhancing the known substance efficacy, including already known property substance, not to be of new use, and already existing process, apparatus or machine, unless the product cannot be anticipated resulting to a "new" creation with application of at least one reactant as "new" for the non-foreseeable process. [2]

### 3.0 FINDINGS

#### Artificial Intelligence

**Table 1: Policy Options Offered by The UK IPO in Computer-Generated Works (Kretschmer, M, Meletti, B, & Porangaba, L. (2022). Artificial Intelligence and Intellectual Property: Copyright and Patents – A Response by the Create Centre to the UK Intellectual Property Office’s Open Consultation. *Journal of Intellectual Property Law & Practice*, Vol. 17(3), Oxford University Press)**

Computer-Generated Works	
Option 0	Make no legal change
Option 1	Remove protection for computer-generated works
Option 2	Replace the current protection with a new right of reduced scope/duration

Based on the study of Kretschmer, Meletti, and Porongaba, pertaining to s 9(3) of the 1988 Copyright, Designs, and Patents Act (CDPA), UK has no corresponding laws comparable to majority of other jurisdictions, hence, this UK law is deemed as unique due to its complexity. As a result, after Brexit, issues concerning this legal provision may seek other particulars of copyright law for effective operation of its corresponding law. Thus, there is an imposed question being developed for legal complexity as to what originality standard must be applied to these issues. Hence, computer-generated outputs must be regarded as authorless works aligned with the criteria for originality involved in literary, dramatic, musical, or artistic (LDMA) creations as matters to be answered restrictedly in UK law. [3]

The standards needed as evidence are high in specifications during this era of rapid industrial change and technological advancements. Thus, the burden of proof points to fundamentally advocate new rights required and the estimated production prices, the people who will avail their invention as consumption. Hence, Option 1 has an invention provision that requires copyright creation to maintain a standard without devotion for a particular creation or work. Otherwise, UK government shall remove their computer-generated AI protection based on s 9(3) for the emergence of substantial evidence in their AI businesses. Furthermore, the UK IPO policy provides Option 2 concerning additional IP rights regarding cumulation issues on reduced duration and scope in processing time that would basically categorize into two types, resulting to expensive prices and loss of invention as reviewed by Gower (2006) and Hargreaves (2011). [3]

In comparison with the Indian Patents (Amendment) Act, under the obligation of WTO for full compliance of TRIPS Agreement, Novartis’ original drug molecule can retain its patentability in the United States. Hence, UK Intellectual Property (IP) Law has strong cohesion of validation pertaining to s 9(3) of the 1988 Copyright, Designs, and Patents Act (CDPA). Therefore, the dramatic work of Glivec, as pharmaceutical art, does not work with computer-generated outputs as copyright of Novartis’ Artificial Intelligence (AI) due to presence of its dedication to people in making life-saving drug. Thus, Glivec, the salt form of Imatinib mesylate, lacks authorless creation, hence, it is ineligible under the standard of innovation evidence of UK law.

## Text and Data Mining

**Table 2: Policy Options offered by the UK IPO in TDM (Kretschmer, M, Meletti, B, & Porangaba, L. (2022). Artificial Intelligence and Intellectual Property: Copyright and Patents – a Response by the CREATE Centre to the UK Intellectual Property Office’s Open Consultation. *Journal of Intellectual Property Law & Practice*, Vol. 17(3), Oxford University Press)**

Text and Data Mining (Tdm)	
Option 0	Make no legal change
Option 1	Improve licensing environment for the purposes of TDM
Option 2	Extend the existing TDM exception to cover commercial research and databases
Option 3	Adopt a TDM exception for any use, with a rights holder opt-out
Option 4	Adopt a TDM exception for any use, which does not allow rights holder opt-out

In UK law of Intellectual Property, extraction of evident materials from already existing copyright-protected creation is not accepted for acquisition of TDM as IP in this pertinent act (Option 2). Hence, in this IP acquisition, industrial firms should present more robust evidence in empirical research, not just only for the requirement of authorless computer-generated works, but also to exhibit more related research on database, otherwise repealed. Moreover, the offered Option 1 should render a lawful access to public interests for legitimacy of its creative environment to be socially immersed as an invention as non-obviousness. [3]

Based on constitutional laws, the amended Patents Act of India is implementing the TRIPS Agreement for global standards of intellectual property. Furthermore, according to s 3(d) of the Indian Act, Glivec fails to conform with cheaper medicine access for legitimacy of public interests as social immersion to non-obviousness work of patentability. Thus, s 9(3) of the 1988 Copyright, Designs, and Patents Act (CDPA) of UK law of Intellectual Property is comparable with s 3(d) of the Patents (Amendment) Act in India.

## Patent Law

**Table 3. Policy Options offered by the UK IPO in Patent Inventorship (Kretschmer, M, Meletti, B, & Porangaba, L. (2022). Artificial intelligence and intellectual property: copyright and patents – a response by the CREATE Centre to the UK Intellectual Property Office’s open consultation. *Journal of Intellectual Property Law & Practice*, Vol. 17(3), Oxford University Press)**

Patent Inventorship	
Option 0	Make no legal change
Option 1	Inventor ‘expanded’ to include humans responsible for an AI system which devises inventions
Option 2	Allow patent applications to identify AI as inventor
Option 3	Protect AI-devised inventions through a new type of protection

In patent inventorship, Option 0 is very substantial in advocating Intellectual Property without any raised issues in their creation. Hence, Artificial Intelligence, as copyright-generated works, has maintained its high quality of research originating from authorless invention in lack of any dedicated working output of human assistance. Moreover, any needed requirements which deemed by the government to be vital in advocating substantive law, may reform the policy in alignment



with the international level in accordance with their own interpretation of constitutional law. Furthermore, the European Patent Office (EPO) clearly stated that only a human being can be an inventor and computer-generated works cannot transfer any rights to a person (Thaler v Comptroller General of Patents). [3]

The Novartis' case review, in comparison with s 9(3) of the 1988 Copyright, Designs, and Patents Act (CDPA) of UK Intellectual Property Law, failed to prove that Glivec serves as a new type of invention. Hence, the inventions of Zimmerman are beyond this pharmaceutical art. Thus, dedication to deliver expensive medicines as life-saving drug is deemed to be unconstitutional due to absence of authorless creation. Therefore, the India's full compliance of global standards based on TRIPS Agreement as obliged member of WTO conforms with the complexity of Intellectual Property policies of UK in Artificial Intelligence pertaining to copyright and invention.

### **Novartis' Argument**

Novartis dissents that there was a sought patent on the original molecule of the drug as protection invention in the United States. The new patent being applied and argued under s 3(d) of Patents Act in India is that Glivec is a viable drug, under "inventive step", processing more stable, and 30% more bioavailable in its formulated salt form. Hence, their drug version must be acknowledged for Indian patent laws based on its marketability to patients.

Furthermore, the drug company contested the validity of s 3(d) under TRIPS Agreement due to the altered drug bioavailability of imatinib that augment to 30%, pointing Art 27 of TRIPS discussing that this legal provision generally ordering patentability to inventions deemed as new, constituting a non-obvious inventive step capable to for utilitarianism of industrial benefits. Moreover, Novartis rejects to accept the court decision of India emphasizing their sentiments to India as a thorn to innovation stifling the research and development process of the pharmaceutical sector, hence, grasping the opinion as wasting the expenses of the company compromising to safeguard the public health based on already existing original drug patent in United States. [6]

### **Indian Government**

India has the legal authority to evaluate standards of invention under flexibility of its supreme powers according to socio-economic conditions of their country alone. Hence, the patent law of India has specified provisions in s 3(d) to forbid patentability of pharmaceutical art, such as 'evergreening' known to just improve the bioavailability of the drug as its purpose of creation and protect the public rights of their citizens on pricing access of medicines. As mentioned in the case, Glivec is a very expensive medicine in their country at a cost of USD \$2,600 per client, which cannot be afforded by an average Indian citizen, stating that their annual income is over three times of its market price. [6]

Moreover, India also asserted that no illegal decisions, such as restraining other constitutional rights, were done and that the TRIPS Agreement is harmonized with DOHA Declaration. The court of India clearly stated that the TRIPS Agreement must be enforced since it interprets, in a supportive manner, the rights of the WTO members to protect their country's public health, specifying that this agreement advocates the access to medicines appropriate to the pricing interests of the public. Therefore, the patent laws of India complied with their constitutional law as argued by the legal representatives of Novartis. [6]

## **Parallel Citations**

The Supreme Court denied the Novartis' argument and ruled that Glivec (Imatinib mesylate) production did not appear to be as a non-obviousness of invention as evaluated by the law of India. Upon dismissal of the appeal of Novartis, the Indian Supreme Court stated:

...we strongly refuse the dissent of Novartis to consider their Glivec as a new drug patent work, and although Zimmerman is the inventor of its other derivatives, it is beyond of his creative invention. [2]

The judicial opinion became apparent as an economical relief for majority of people to gain access with pricing treatment as medicines are interpreted to be made affordable to millions of citizens all over the world, hence, controlling pharmaceutical industries from 'evergreening' as works of art, not eligible for patentability. Furthermore, the court exercised their constitutional laws implementing the affordability of Glivec, as life-saving drug, hence, protecting the public health of their citizens in advocacy of cheaper access to medicines. Therefore, the legal claims of Novartis were refused based on s 3(d) of the Indian Patents Act as amended and complied with international laws. [7]

## **4.0 CONCLUSION AND RECOMMENDATIONS**

Shepard's validation answers question development in legal research methodology. Parallel citations are vital in comparison with the references used for argument exhibition of cohesion showing syllogisms and deductive reasoning. Intellectual Property must be constitutionally elevated in a high standard manner showing authorless works in doctrinal and empirical analyses. Therefore, patent law must advocate works of art towards technological advancements for the goal of monetary success under business law. The economic success of a country is recommended to follow the objectives of business ethics as tools for socio-legal monitoring of public welfare and safety. The law adopts and embraces industrial change for convenience as a form of creation under pre-emptive doctrine of their constitution. Thus, it is highly recommended to value research and development in such a way of not focusing on monetary profits alone, rather, promote business ethics as its highest goal through utilization of abundant resources in a natural manner of time, in lack of any devotion, without any anticipation or using existing already formed creation towards economic gains.

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