Actor Network Theory Analysis of the Novartis Infringed Drug Patent

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By

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

In 2021, Novartis was ordered to pay $177.8 million in addition to royalties for infringing upon Plexxikon's patent. The current findings for this case blame Novartis for the failure to be the novel owners of its commercialized drug Tafinlar. As legal interpretations between Novartis and Plexxikon have been released, the final ruling has been upheld as the chemical compound was similar and the location in which sales were occurring overlapped with Plexxikon (Rosenblatt, 2019). Although Tafinlar was being sold commercially by Novartis, it was originally developed by GlaxoSmithKline (GSK). In 2015 GSK sold its oncology portfolio, which included the drug Tafinlar. GSK developed this drug after its prior partnership with Plexxikon (GlaxoSmithKline, 2015). In addition, GSK won patent approval for the drug's chemical compound in 2013, which was 2 years after Plexxikon received approval for the same chemical compound (Dunleavy, 2021). However, GSK willingly sold this drug to Novartis as it helped its vaccine portfolio and overall revenue growth. Considering the aforementioned involvement of GSK's overall role in submitting a patent with the same chemical compound to the USPTO should, in turn, alter the perception of blame Novartis faced for infringement. Therefore, the legal interpretation fails to identify the role of GSK, USPTO, and the sales and profits that contributed to Novartis's infringement prior to and after its acquisition of Tafinlar from GlaxoSmithKline.

To analyze Novartis's patent drug infringement, I will utilize Actor-Network theory (ANT) to argue that GSK, rather than Novartis, USPTO, sales and profits, chemical compound, or GSK engineers are the factors that ultimately led to Novartis being able to fully benefit from its commercialization of Tafinlar. Actor-Network Theory describes the activity of a network builder who assembles a network that includes both human and non-human actors that seek to accomplish a particular goal (Callon, 1987). I will begin by laying out the general network of human and

nonhuman actors and by emphasizing Novartis as the original primary actor. Next, I will outline the underlying motives for GSK to sell its oncology portfolio. I will then deconstruct the network by pointing out specific instances in which the mutual relationships GSK had with the USPTO and Novartis ultimately failed by the inability to perform their desired roles. Through this analysis, I will spotlight how GSK dominated the other actors while monetarily benefiting from its sale with Novartis, which represents its failure to provide adequate information to the USPTO and Novartis. By utilizing relevant news articles, court documents, company testimonies, and investment data the network will be described.

Background

Plexxikon Inc. created a chemical compound to combat skin cancer in the early 2000s. In 2005, it filed for patents and won approval for Zelbraf, a skin cancer drug, in 2011. In 2015 a competitor, Novartis, acquired Tafinlar from GlaxoSmithKline, which was a similar drug to Zelbraf and had received its patent approval in 2013. Tafinlar was filed to the US Patent and Trademark Office in 2008, three years after Zelbraf. Novartis began profiting from this drug; subsequently, Plexxikon Inc. filed a lawsuit claiming infringement upon two patents. This infringement led to a lengthy trial consisting of multiple court appeals and a final ruling in favor of Plexxikon Inc. This ruling cost Novartis a grand total of $178 million (Dunleavy, 2021).

Literature Review

Several legal scholars have completed an in-depth analysis of the primary factors involved in Novartis's infringement of Plexxikon Inc. patents that resulted in a corporate failure. They state that the failure is related to its infringed patents as opposed to the actions of the original developers of the drug and the US Patent and Trademark Office. When medicinal patents are infringed, it is normally due to a technical reason. However, this notion overlooks the authors' failure to research

the large corporation during the acquisition of Tafinlar. Consequently, Novartis was unable to maximize profits when commercializing the novel drug.

In *Is the Chemical Genus Claim Really "Dead" at the Federal Circuit,* Christopher Holman outlines a detailed explanation for the infringement of Plexxikon's patent, explaining the technical factors that overlap between the drugs (Holman, 2022). He remarks that the case was rare as it consisted of a structural genus claim, which is a claim that covers a group of related chemicals in the commercialization of its drug and was found infringed and invalid after being challenged for a supposed failure to respect the enablement and written description requirements. While he provides insight into the infringement of two novel drugs used for different purposes, he avoids discussion of the moral capability of the former drug developers at GlaxoSmithKline (GSK) and whether Novartis was willingly generating revenue with such knowledge.

Jennifer Rosenblatt, Professor at Fordham Law, reported in *The Aftereffects of TC Heartland: How to Effectively Dismiss and Motions to Transfer on the Basis of Improper Value* that the United States District Court of the Northern District of California agreed with the infringement allegations. Furthermore, she states, "The district court reasoned that allegations of infringement existed through sales and offers for sale of the allegedly infringing product, were sufficient to satisfy the requirement of an act of infringement pursuant to the second prong of the patent venue statue" (Rosenblatt, 2019). A second prong of the patent statue provides that the venue is proper in districts where past acts of infringement have occurred. While this report continues to support that Novartis infringed on Plexxikons patent, it fails to discuss whether the drugs were being used for the same clinical application.

Unquestionably, there is a great deal of knowledge that can be obtained from the ruling of the infringement between Plexxikon and Novartis; however, the other actors within the system that

played a role in the economic failure of such a large corporation must be explored. Rosenblatt's and Holman's analysis of the court's rulings fail to consider Novartis's acquisition of GSK, corporate glorification, and the oversights of the US Patent and Trademark Office. This paper will provide an explanation for the focus on the scientific replication resulting in an infringed patent but will also use Actor-Network theory to determine who must be accounted for when commercializing a therapeutic drug.

Conceptual Framework

The systematic failure that occurred for Novartis Inc. can be analyzed using the science, technology, and society (STS) Actor-Network theory framework. Michel Callon's theory describes the activity of a network builder who assembles a network that includes both human and non-human actors that seek to accomplish a particular goal (Callon, 1987). This systematic model includes complex social, economic, technical, and political elements that are all connected.

1. Social
2. Technical
3. Economic
4. Political
5. Conceptual
6. Natural

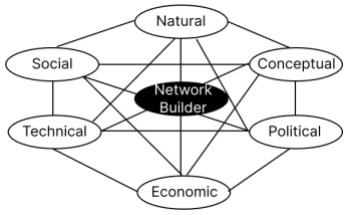

Figure 1: Michel Callon's Actors within a Network

I will use Callon's concept of translation, which refers to the process of forming and maintaining an actor-network. Translation is laid out in four phases: problematization, interessement, enrolment, and mobilisation. Problematization can be broken down into two components. The first component is that primary actors define a captivating problem and determine the human and non-human actors needed to solve it. Furthermore, they define the roles and interests of other actors within the network and how the actors are interconnected with one another. The second component consists of the obligatory passage point, which forces actors to

converge on the network builder. Interessement is described as profit-sharing where the primary actors attempt to recruit other actors into the network by dislocating them from other competing networks and persuading them to adopt and align their interests with the primary actors. Enrolment is the process of negotiations, trials of strength, and tricks that accompany the interessements and enable them to succeed (Callon, 1984). At this point the actors accept their roles and begin to perform them within the network. Mobilisation is when the controlling actors modify the behavior of all other actors to secure their role of speaking for them. Construction of a heterogeneous network will be important to determine the association between the relevant human and non-human actors. A network is capable of failing, however, if one or more actors refuse or fail to perform the roles assigned by the primary actors.

By using this concept, I aim to examine the roles of non-human and human actors within Novartis's network to determine who must be accounted for when selling a pharmaceutical drug to the public market. Callon's concept of translation will be utilized to determine at which point the system ultimately failed. ANT will be used to evaluate multiple factors before and after the acquisition of Tafinlar by Novartis such as the technical, social, economic, and conceptual actors that contributed to the company's failure relating to the infringed patent.

Analysis

Network Formation

In order to determine the root causes for Novartis's failure, the first step will be to recreate the actor-network by identifying the heterogeneous actors involved. I have identified through court documentation human and non-human actors that were ignored in the downturn of Novartis (Plexxikon Inc. V. Novartis Pharm. Corp., 2021). These human actors are as follows: (i) *GlaxoSmithKline (GSK),* a pharmaceutical company that allowed Novartis to acquire Tafinlar; (ii)

engineers who worked for GSK; (iii) the *Novartis team* involved with mergers and acquisition; and (iv) the *Patent and Trademark Office* responsible for filing novel patents. In addition, the non-human actors are as follows: (v) *patent of chemical compounds* used for drug development and (vi) *sales and profits* for each company's stakeholders.

The next step is to determine the hierarchical organization and interconnected network by using the four phases of translation. The US District Court judge Gilliam Hayword Jr.'s order regarding the plaintiff's motion in liminine number one and the defendant's motions in liminine numbers two, three, and four can be used to outline these phases (Plexxikon Inc. V. Novartis Pharm. Corp., 2021). In the court filings, it is broadly acknowledged that Novartis acquired Tafinlar from GSK, and its internal team failed to recognize an already patented chemical compound owned by Plexxikon. Therefore, analyzing the human actors specifically from this court documentation leads to the assumption that the Novartis mergers and acquisition team is the primary actor around which the infringement actor-network formed through translation.

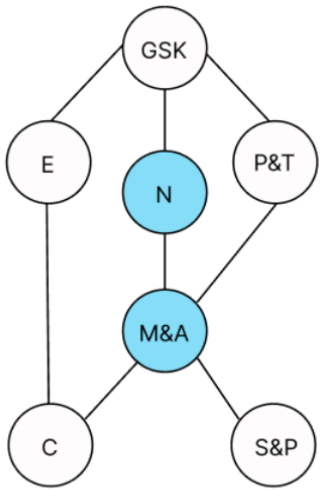

Figure 2 - The general Novartis drug patent infringement actor-network. GSK is GlaxoSmithKline, E is engineers at GSK, P&T is the US Patent and Trademark Office, N is Novartis, M&A is Novartis merger and acquisition team, S&P is sales and profits, and C is chemical compounds.

The general Novartis patent drug infringement actor-network is outlined in Figure 2. Specifically, the primary actor is the Novartis M&A team, which is highlighted in blue. The connections are all mutually associated. Problemization is the first phase of translation. Within this phase, the mergers and acquisition team for Novartis determined that the drug Tafinlar would be very profitable for patients with lung cancer and help its company's revenue growth. This introduces the problem that Novartis acquired a drug from GSK that its company sold and used to

develop other drugs. However, its M&A team failed to do research into the origination and engineers who developed the chemical compound. Furthermore, GlaxoSmithKline (GSK), a pharmaceutical company, willingly sold a drug it had developed based on a partnership it once had with Plexxikon. In Figure 2, sales and profits were a motive for Novartis's acquisition of GSK's drug. In addition, the US Patent and Trademark Office had an opportunity to notice similarities in GSK's patent to Plexxikon in 2008 as well as during the change of ownership in 2015 ("Patents Assignments," 2019).

Interessement or profit-sharing is the second phase, in which the Novartis M&A team recruited other actors to participate in the network by aligning their interests with those of the primary actors. The mergers and acquisition team first recruited GSK, which had a novel drug ready for commercialization and a chemical compound that can be utilized for other cancer applications. In order for this acquisition to occur, GSK had its engineers develop Tafinlar and had its chemical compound approved by the US Trade and Patent Office. Finally, the acquisition occurred since the sale benefited GSK and helped Novartis's sales and profits in the long term (Novartis, 2015).

The next phase is enrollment, in which GSK and its engineers, Novartis's mergers and acquisition team, and the US Patent and Trademark Office would "ideally" accept and perform their assigned roles and form mutual relationships with the other actors in the network. Theoretically, the engineers and executive team at GSK knew of the reuse of Plexxikons chemical compound, received a patent, and willingly sold its product to Novartis, which did not perform adequate research. Novartis then sold Tafinlar and made substantial profits. GSK in this instance had the largest control over how the network would be connected. This in turn allowed for the

cooperation of the US Patent and Trademark Office, Novartis, and the other non-human actors that played a role in the infringement of Plexxikon's patent.

Acquisition

Before I break down the actor-network, I will first outline the motivations for GSK to sell off its oncology portfolio to Novartis, which included the drug Tafinlar. In summary, GSK sold its oncology products and respective R&D activities for $16 billion dollars to help increase revenue and decrease supply costs in its vaccine and consumer healthcare units (GSK, 2014). This transaction immediately allowed GSK to grow its revenue by $1.3 billion annually. In addition, five years after the transaction, GSK estimated that it would save $1 billion that could be allocated to support innovation and new product launches. After the transaction was completed, shares in GSK rose 5.2%. Correspondingly, GSK shareholders benefited from a $4 billion capital return funded by the deal with Novartis (Butler, 2014). When analyzing these findings, it is apparent that Novartis's acquisition of the oncology portfolio substantially benefited GSK as it allowed the company to reduce costs while increasing revenue and in turn satisfying its shareholders. While GSK made $16 billion in this transaction, it also bought Novartis's vaccine branch for $7 billion. At the time of the acquisition in 2015, GSK's annual revenue was $35.971 billion, and today it is over $44 billion (Zacks Investment Research, Inc., n.d.). When specifically looking at revenue growth for its revamped vaccine group, sales grew 14% in 2016, 27% in 2017, and have continued to grow through 2022 (Sagonowsky, 2018). GSK has prioritized its growth in vaccines as this was the company's goal in its transaction with Novartis (Helfand, 2014). Given this steady revenue growth, GSK took advantage of the deal as it knew Tafinlar was created based on its prior partnership with Plexxikon (Dunleavy, 2021). Therefore, GSK went through with a deal for economic gain while negatively affecting its transactional partner Novartis, which would later be

proven guilty of infringement. I will now discuss how GSK's company growth and avoidance of sharing the knowledge of an infringed patent shaped the overall actor-network.

Failure to Perform Roles

When compiling the Novartis drug patent infringement actor-network, I stated in the enrollment phase that each primary actor would "ideally" perform its assigned roles and create mutual relationships with the other actors in the network. However, the actual actor-network stalled and became imbalanced during enrollment because of GSKs underlying motives to capitalize on a deal that involved an undisclosed infringed patent. Figure 3 outlines the imbalanced actor-network that actually existed during this transaction between Novartis and GSK. Arrows are drawn to represent the primary direction of a positive relationship between any two actors. The solid arrows symbolize a strong constructive association where an actor relays information and it is accepted by another actor. The dotted arrows symbolize desired associations within the network. The colors of each actor were selected to distinguish their roles within the network, which resulted in an imbalance. Here, Red signifies the primary actor; blue represents the Novartis acquisition team; and green is the underlying group of actors. In order for the network to be mobilized, continual communication through the primary actor or OPP is necessary (Callon, 1986). Therefore, each human actor is still bidirectionally connected.

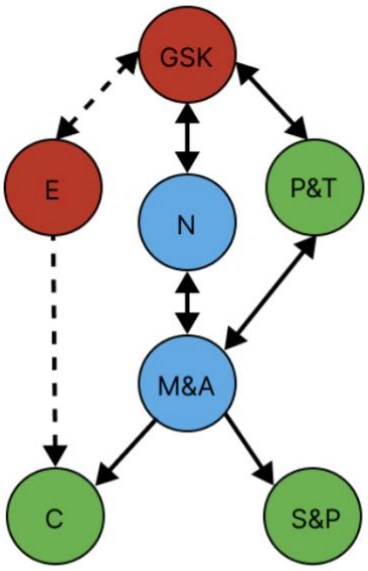

Figure 3 - The imbalance Novartis drug patent infringement actor-network. GSK is GlaxoSmithKline, E is engineers at GSK, P&T is the US Patent and Trademark Office, N is Novartis, M&A is Novartis merger and acquisition team, S&P is sales and profits, and C is chemical compounds.

The most important associations to take note of are those between GSK, Novartis's M&A team, and the US Patent and Trademark Office, along with the relationships of the nonhuman

actors. Since GSK was the primary actor in the transaction with Novartis, it has bidirectional associations with Novartis and the US Patent and Trademark Office that could have prevented the infringed patent Novartis faced for commercializing Tafinlar.

I will first discuss GSK's inability to inform Novartis that the drug, Tafinlar, was derived from a chemical compound stolen from a partnership it had with Plexxikon. Novartis was punished for an infringed patent due to GSK's and Plexxikon's short-term project. The failed bidirectional relationship can be seen in figure 3 where GSK and its engineers are in red, and Novartis and its M&A team are denoted in blue. The Plexxikon Inc. V. Novartis Corp (2021) court case states:

> The defendant acknowledged that it received a summary of the "freedom to operate" analysis ("FTO summary") prepared as part of the GSK transaction. However, Defendant stated that this FTO summary is privileged and that it did not have any other responsive, non-privileged documents itself. It later produced the publicly available Sale and Purchase Agreement ("SAPA") for the GSK transaction, which was filed with the United States Securities and Exchange Commission. The SAPA contains a warranty from GSK that the products in its oncology portfolio -including Tafinlar- did not infringe any intellectual property rights of any third party. (p. 4)

It is important to note that Novartis received a warranty in the acquisition of GSK's oncology portfolio that ensured no products were infringed upon. This warranty was even approved by the United States Securities and Exchange Commission, which had oversight in the Sales and Purchase Agreement. Therefore, Novartis truly believed it was acquiring a drug that was novel and did not infringe on a genus claim. In addition, this reiterates that GSK did not disclose all documentation involved in the development of Tafinlar. In order for the actors to accept and perform their assigned roles, GSK should have been more transparent, and Novartis should have done a due diligence

analysis. Due to this lack of attention to detail, GSK profited while Novartis paid a large settlement and will continue to pay royalties to Plexxikon.

Examining the United States Patent and Trademark Office's (USPTO) involvement with GSK's patent of Tafinlar and its role in Novartis's acquisition brings light to the mutual relationships that were never created between the actors (Figure 3: P&T in green). The USPTO approved a patent for GSK in relation to the chemical compound of Tafinlar in 2013 (Dunleavy, 2021). However, two years prior, in 2011, Plexxikon received a patent for a similar drug compound. Per USPTO guidelines, a claimed invention cannot be filed after the effective filing date of a claimed invention ("General Information Concerning Patents," 2023). Based on the timeline of events, when GSK submitted its patents to the USPTO the overlap should have been noticed, and its patent should not have been approved (Figure 3: red and green constructive relationship). Consequently, the patent was approved, and in 2015 GSK sold its patent with other oncology products to Novartis. When the acquisition occurred, the USPTO again failed to perform its role. When a patent is transferred from one organization to another, the original owner has to record the change of ownership (assignment) with the USPTO's Assignment Recordation Branch by filing a Recordation Cover Sheet along with a copy of the actual assignment ("Patents Assignments," 2019). The responsibility of the Assignment Recordation Branch is to review the change of ownership; however, it did not recheck to ensure the patent being transferred was not infringed (Figure 3: green connection with blue and red). If the USPTO had an investigation division for these transfers, the acquisition may have been halted as Novartis would have been notified of the infringed chemical compound. Instead, GSK knowingly received approval for a patent that was made based on prior art, which ultimately led to the court's ruling that Novartis infringed on Plexxikon's patent and that no other actors were responsible.

Chemical Compound

The Novartis network deconstructed above (Figure 3) identifies GSK as the primary actor responsible for Novartis's infringed patent. However, a counterargument would be to blame Novartis and its Mergers & Acquisition Team (Figure 2) for not performing adequate research into the chemical compounds and focusing its sole attention on the monetary outcomes. This claim suggests that GSK was not responsible for disclosing information to the USPTO or Novartis about the reuse of a chemical compound from prior work with Plexxikon. Instead, this counterargument makes Novartis the actor that commercialized the chemical compound for profit as it wanted to focus on the economic actor (sales and profits) that would satisfy its shareholders. However, this perspective fails to address economic gains GSK made by selling its oncology portfolio, which was presented in the Network Formation above. At this point, it is important to analyze the overall timeline of events when determining the primary actor responsible. In other words, if GSK had performed its assigned role, it would not have submitted a patent that was knowingly made based on a preexisting chemical compound, nor would GSK have sold its oncology portfolio with an infringed patent to Novartis for an economic gain. It is not surprising that GSK took advantage of its relationships that other actors in the network believed were mutual (Figure 3). It is not the acquiring organization's (Novartis) primary responsibility to verify the origin of a drug, but rather it is GSK's responsibility to sell non-infringed drugs.

Conclusion

In this paper, I utilized the sociotechnical concept of Actor-Network theory to compile and deconstruct the Novartis drug patent infringement actor-network in order to determine the actual reason for infringement. Through an analysis of the monetary gains for GSK to sell its oncology portfolio, which included Tafinlar, it is evident that GSK is at fault. Furthermore, through the

phases of translation, I was able to break down how the USPTO and Novartis's M&A team failed to perform their roles as a result of GSK's decisions within the enrollment phase. This shaped how GSK's actions affected the overall Novartis drug patent infringement network and how its ulterior motives were ignored. With this knowledge, readers interested in the acquisition of a patented pharmaceutical drug need to be proactive in ensuring all information related to the drug has been disclosed, no overlap exists in the chemical compound, and that the USPTO has not approved a patent that overlaps with an existing one. While current case studies and conversations attribute Novartis's failure to commercialize Tafinlar to an infringed patent, I have introduced multiple human and non-human factors that remove Novartis from such blame. As more analysis of this case evolves, this study can be utilized to put GSK at fault.

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